



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 15 1994

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Tamima Itani, Ph.D.
Program Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, Illinois 60073

Re: K940147
Auto Syringe® AS40A Infusion Pump
Regulatory Class: II
Dated: January 7, 1994
Received: January 11, 1994

Dear Dr. Itani:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

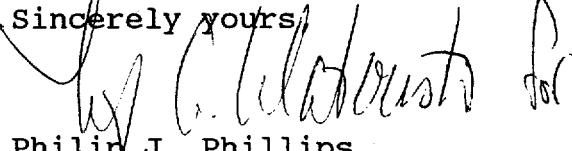
This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being

1

Page 2 - Tamima Itani, Ph.D.

approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Promotion and Advertising Policy Staff, (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,


Philip J. Phillips
Acting Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health



Memorandum

Date

4/11/94

From

REVIEWER(S) - NAME(S)

Wolanski

Subject

510(k) NOTIFICATION

K940147

To

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- ☒ (A) Is substantially equivalent to marketed devices.
- ☐ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- ☐ (C) Requires more data.
- ☐ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☒

This 510(k) contains: (check appropriate box(es))

- ☒ A 510(k) summary of safety and effectiveness, or
- ☐ A 510(k) statement that safety and effectiveness information will be made available
- ☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

- ☐ No Confidentiality
- ☐ Confidentiality for 90 days
- ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

880.5725 PRN Class II

Additional Product Code(s) w/panel (optional):

REVIEW:

(BRANCH CHIEF)

BRANCH CODE

(DATE)

FINAL REVIEW:

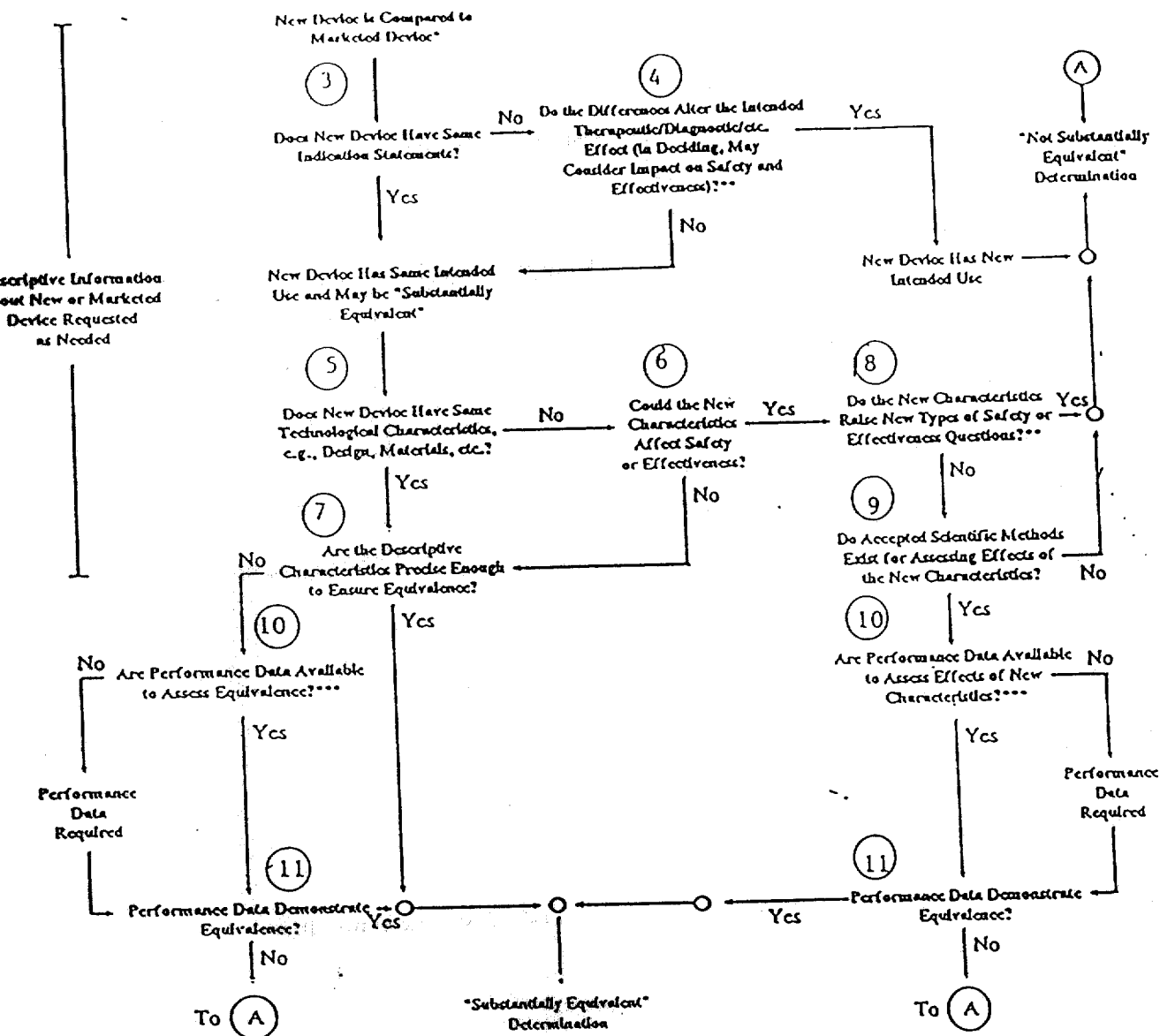
(DIVISION DIRECTOR)

(DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

REVIEWER: Wolanski DIVISION/BRANCH: DGRD / 6HDB
 TRADE NAME: Auto Syringe AS 40A COMMON NAME: Syringe infusion pump
 PRODUCT TO WHICH COMPARED: K903343 K911289 K905029
 (510(k) NUMBER IF KNOWN)

- | | YES | NO | |
|--|-------------------------------------|-------------------------------------|--|
| 1. IS PRODUCT A DEVICE? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | - IF NO STOP |
| 2. DEVICE SUBJECT TO 510(k)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | - IF NO STOP |
| 3. SAME INDICATION STATEMENT? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | - IF YES GO TO 5 |
| 4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | - IF YES STOP - NE |
| 5. SAME TECHNOLOGICAL CHARACTERISTICS? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | - IF YES GO TO 7 |
| 6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS? | <input type="checkbox"/> | <input type="checkbox"/> | - IF YES GO TO 8 |
| 7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH? | <input type="checkbox"/> | <input checked="" type="checkbox"/> | - IF NO GO TO 10
- IF YES STOP - SE |
| 8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS? | <input type="checkbox"/> | <input type="checkbox"/> | - IF YES STOP - NE |
| 9. ACCEPTED SCIENTIFIC METHODS EXIST? | <input type="checkbox"/> | <input type="checkbox"/> | - IF NO STOP - NE |
| 10. PERFORMANCE DATA AVAILABLE? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | - IF NO REQUEST DATA |
| 11. DATA DEMONSTRATE EQUIVALENCE? | <input checked="" type="checkbox"/> | <input type="checkbox"/> | SE |

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

1. INTENDED USE: Continuous or intermittent infusion of IV drug solutions
via intravenous, intra-arterial, epidural or subcutaneous routes of
administration to deliver whole blood or packed red blood cells
or can be piggybacked onto an ongoing IV line

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY:

See Review memo section N

6

1. EXPLAIN WHY NOT A DEVICE: _____

2. EXPLAIN WHY NOT SUBJECT TO 510(k): _____

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION: _____

See Review memo

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE: _____

See Review memo

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: _____

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS: _____

7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: _____

see review memo

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW: _____

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED: _____

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED: _____

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT: _____

see review memo

ATTACH ADDITIONAL SUPPORTING INFORMATION

8

MEMO TO THE RECORD
510(K) REVIEW

K940417

DATE: April 11, 1994
FROM: Nicole Wolanski

OFFICE: HFZ-410
DIVISION: DGRD/GHDB

COMPANY NAME: Baxter Healthcare Corporation
DEVICE NAME: Auto Syringe AS40A

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

The AS40A is a syringe pump which provides for accurate infusion. This device accepts standard disposable syringes from 1 to 60 mL in size.

2. INTENDED USE:

The pump can be used for continuous or intermittent infusion of intravenous drug solutions via intravenous, intra-arterial, epidural or subcutaneous routes of administration; to deliver whole blood or packed red blood cells; or can be piggybacked into an ongoing IV line to automatically, precisely and economically deliver secondary solutions. This device is indicated for the neonate and pediatric populations

3. DEVICE DESCRIPTION:

- A. Life-supporting or life-sustaining: No
- B. Implant (short-term or long-term): No
- C. Is the device sterile? No
If yes, is sterility information provided?
- D. Is the device for single use? No
- E. Is the device for prescription use? Yes
If yes, is prescription labeling included? Yes
- F. Is the device for home use or portable? Yes

9

- G. Does the device contain drug or biological product as a component?
No
- H. Is this device a kit? No
If yes, and some or all of the components are not new, does the submission include a certification that these components were either preamendment or found to be substantially equivalent?
- I. Software-driven: Yes
Estimated level of concern: Major
Has the firm provided a hazard analysis, software requirements and design information, adequate test plans/protocols with appropriate data and test reports, documentation of the software development process including quality assurance activities, configuration management plan, and verification activities and summaries, commensurate with the level of concern, as discussed in the Reviewer Guidance for Computer Controlled Medical Devices?
Yes, this pump was approved under K903343. This submission is for a change in intended use. All changes to the software have been made according to software change and validation procedures.
- J. Electrically Operated: Yes
If yes, are AAMI or IEC leakage currents met and is the test protocol, data, and results provided? No electrical modifications have been made.
- K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): AAMI draft
- L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status:

K903343 - Auto Syringe Infusion Pump, Baxter Healthxcare Corp.
K911289 - Auto Syringe Infusion Pump, Baxter Healthxcare Corp.
K905029 - Model 2001 Syringe Infusion Pump, Medfusion
- M. Submission provides comparative specifications a Yes
comparative in vitro data b No
performance data c Yes
animal testing d No
clinical testing e No
biocompatibility testing f No*


*The materials have not changed, only the intended use.

- a. A comparison of similarities and differences (features, specifications, intended use, materials, design, theory of operation, accessories, etc.) in tabular form should be included. Differences should be explained with supporting rationale and/or data. If differences include new intended
- D

use or new technological characteristics, clinical data would be needed to demonstrate that no new issues of safety and effectiveness are raised. If reference literature is accepted by the FDA to support any differences, copies of the articles must be provided as opposed to listing the author and titles, the significant areas of the articles must be highlighted, and a summary must be provided relating the information to the issue at hand, including a discussion of the study protocol, data, statistical analyses, and a summary of the results.

- b. If applicable, comparative bench testing including protocol, data, and a summary of the results should be provided.
 - c. Performance data including protocol, data, and summary explaining how testing and data demonstrate that the device performs as intended should be provided.
 - d. If applicable, animal testing including protocol, data, and a summary of the results should be provided.
 - e. If applicable, clinical testing, including the investigational plan, data, statistical analyses and a summary of results should be provided. If the study was performed under an investigational device exemption (IDE), the IDE number should be provided. If the device is nonsignificant risk, the study should be conducted under the auspices of the institutional review board (IRB) even though an IDE would not need to be filed with the FDA.
 - f. If applicable, biocompatibility testing, including the protocol for each test required as outlined in the Tripartite Biocompatibility Guidance, the pass/fail criteria, data, and a summary of results should be provided.
- N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

This device is identical to the predicate device Auto Syringe AS40 Pump (K903343) in method of operation, product design, and materials. The only difference is that the new pump extends the indications to include the administration of whole blood and blood products. This modification has had no impact on the software or the hardware of the device. The results of performance testing have been included, demonstrating that hemolysis is at an acceptable level and that the pump is capable of flow rates appropriate for blood delivery (in nonacute trauma situations), Therefore no new types of safety and effectiveness questions exist.



Page 4 of 510(k) review

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes

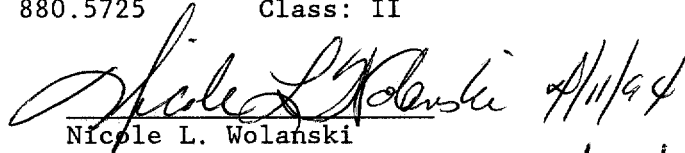
P. RECOMMENDATION:

I believe that this device is equivalent to: 80 FRN

Classification should be based on:

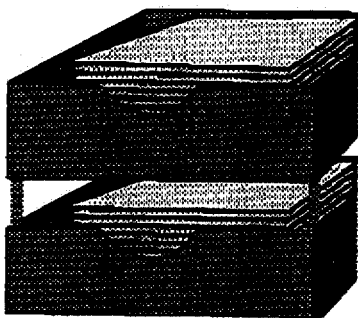
880.5725

Class: II


Nicole L. Wolanski

7/11/94
7/12/94 HED.

18

**Telecopy****Baxter Healthcare Corporation****IV SYSTEMS DIVISION****Round Lake, IL 60073****Regulatory Affairs****DATE:** April 5, 1994**Pages Following:** 2**TO:** Ms. Nicole Wolanski**COMPANY:** FDA**FAX NO.:** (301) 594-2358**PHONE NO.:** (301) 594-1230**FROM:** Tamima Itani**FAX NO.:** (708) 270-4668**PHONE NO.:** (708) 270-4013**SUBJECT:** K940147**COMMENTS:****--- CONFIDENTIAL ---**✓ **Original will follow by:****Original will not follow****Regular Mail**✓ **Federal Express****Other**

I.V. Systems Division

Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

708.546.6311

Baxter

April 5, 1994

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center, HFZ-401
1390 Piccard Drive
Rockville, MD 20857

Attention: Ms. Nicole Wolanski

Re: 510(k) K940147

Blood Infusion Indication for Auto Syringe® AS40A Infusion Pump

Via FAX: (301) 594-2358

(hard copy will follow via Federal Express)


Dear Ms. Wolanski:

As you pointed out during our telephone conversation on April 5, 1994, there is a calculation mistake on page 2 of our March 11, 1994 letter to you. Following is the corrected information. I apologize for the error and the inconvenience it may have caused.

Typically, blood is infused from a blood bag by drip. Compare the delivery rates from gravity infusion and from infusion via a syringe infusion pump.

Typical drip infusions of blood involve containers that contain 250 to 300 ml of blood. The duration of the infusion may be as short as approximately 5 minutes in acute trauma situations, or a maximum of 4 hours (AABB recommendation¹, excerpt attached). This translates into a minimum rate of 62.5 ml/hr (250 ml over 4 hours) and a maximum rate of approximately 3,600 ml/hr (300 ml over 5 minutes). In comparison, the delivery rate range of the syringe infusion pump is from 0.01 ml/hr to 360 ml/hr, and the delivery rate range of our Flo-Gard® 6201 and 6301 volumetric infusion pumps,

¹ American Association of Blood Banks: Technical Manual. 11th Edition. pp. 420-422. 1993.



Ms. Nicole Wolanski
K940147
April 5, 1994
Page 2

Baxter

cleared under 510(k)s K915522 and K915523 respectively and indicated for the infusion of blood, is 1 ml/hr to 1999 ml/hr.

If you have any questions during your review of this response, please contact me at (708) 270-4013. Alternately, you may contact Marcia Marconi, Director, Regulatory Affairs, at (708) 270-4637.

Sincerely,

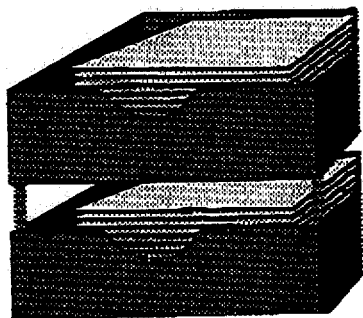
Tamima Itani

Tamima Itani, Ph.D.
Program Manager
Regulatory Affairs
(708) 270-4013
(708) 270-4668 (FAX)

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** TOTAL PAGE.003 **



**Telecopy****Baxter Healthcare Corporation****IV SYSTEMS DIVISION****Round Lake, IL 60073****Regulatory Affairs****DATE:** April 4, 1994**Pages Following:** 6**TO:** Ms. Nicole Wolanski**COMPANY:** FDA**FAX NO.:** (301) 594-2358**PHONE NO.:** (301) 594-1230**FROM:** Tamima Itani**FAX NO.:** (708) 270-4668**PHONE NO.:** (708) 270-4013**SUBJECT:** K932477**COMMENTS:****--- CONFIDENTIAL ---**✓ Original will follow by:Original will not follow

Regular Mail

✓ Federal Express

Other

Up

I.V. Systems Division

Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

708.546.6311

Baxter

April 4, 1994

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center, HFZ-401
1390 Piccard Drive
Rockville, MD 20857

Attention: Ms. Nicole Wolanski

Re: 510(k) K940147
Blood Infusion Indication for Auto Syringe® AS40A Infusion Pump

Attachments

Via FAX: (301) 594-2358
(hard copy will follow via Federal Express)


Dear Ms. Wolanski:

I am providing additional information as requested by you in our telephone conversation on March 21, 1994. Your questions are repeated in bold.

Does the Auto Syringe® AS40A Infusion Pump meet the AAMI standards?

The original 510(k) for the Auto Syringe AS40A Infusion Pump was cleared on July 17, 1990. At that time, the AAMI standards were still in draft form. The draft standards were used to identify the relevant areas for testing. These areas were evaluated using our own internal test methods. The first Auto Syringe® AS40A Infusion Pumps were sold in March of 1992. The AAMI standards were not approved till August of 1992, and were not published till 1993. The changes that are the subject of this 510(k) do not involve any hardware or software changes and therefore did not require any retesting.

Provide a certification that changes made to the software since the original 510(k) submission were made according to software change and validation standard operating procedures.



K940147
Amendment
April 4, 1994
Page 2

Baxter

A certification appears in Attachment 1.

It is stated that standard syringe sizes 1 cc through 60 cc may be used with the pump. Can any size 1 cc to 60 cc be used with the pump?

The Operator's manual is specific about the types of disposable syringes to be used with the Auto Syringe AS40A infusion pump. On page 13 of the current manual, the disposable syringes that may be used with the pumps are listed and are as follows:

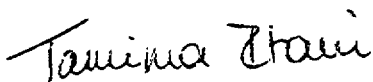
B-D Plastipak® (Becton Dickinson): 1, 3, 5, 10, 20, 30, 60 mL
Monoject® (Sherwood Medical): 1, 3, 6, 12, 20, 35, 60 mL
Terumo® (Terumo): 1, 3, 5, 10, 20, 30, 60 mL

A copy of page 13 appears in Attachment 2.

New disposable syringes introduced by the above-listed manufacturers that have a volume between 1 and 60 cc may be added to the list in the future.

I hope that I have adequately answered all your questions. If you have any additional questions during your review of these responses, do not hesitate to contact me at (708) 270-4013. Alternately, you may contact Marcia Marconi, Director, Regulatory Affairs, at (708) 270-4637.

Sincerely,



Tamima Itani, Ph.D.
Program Manager
Regulatory Affairs
(708) 270-4013
(708) 270-4668 (FAX)

K940147
Amendment
April 4, 1994
Page 3

Baxter

Attachment 1

Certification

19

K940147
Amendment
April 4, 1994
Page 4

This is to certify that Baxter Healthcare Corporation followed and met the software validation and maintenance standard operating procedures that apply to the Auto Syringe AS40A infusion pump. The current procedures are updated versions of the ones submitted in the original 510(k) for the AS40A.

Marc Mandro 4/1/94
Marc Mandro Director of Engineering

20

K940147
Amendment
April 4, 1994
Page 5

Baxter

Attachment 2

Page 13 of Current Operator Manual

21

General Device Information

Technical Specifications

Model:	AS40A Infusion Pump.
Catalog Code:	<ul style="list-style-type: none">• 1M8565 = with Drug Library Option• 1M8560 = without Drug Library Option (upgradable to 1M8565).
Size:	approx. 3.4" x 2.6" x 10" (8.6 x 6.7 x 25 cm)
Weight:	approx. 2.75 lbs. (1.25 kg)
Accuracy:	+/- 3% (not including syringe tolerance) For volume infusions: +/- 3%, or .007" of travel, whichever is greater (not including syringe tolerance).
Syringes:	B-D Plastipak®, 1, 3, 5, 10, 20, 30, 60 mL Monoject®, 1, 3, 6, 12, 20, 35, 60 mL Terumo®, 1, 3, 5, 10, 20, 30, 60 mL
Flow Rate Range:	0.01 mL/hr to 360 mL/hr (dependent on syringe size).
Deliverable Volume:	The full syringe volume can be delivered.
Data Display:	Self-prompting, multi-field LCD (Liquid Crystal Display)
Status Display:	Nine-LED (Light Emitting Diode) array
Power Requirement:	<ul style="list-style-type: none">• AC: 105-125V 60 Hz (battery charger)• DC: internal nickel-cadmium battery pack
Battery Life:	12 hours of operation at 2 mL/hr using a 60 mL syringe, following a 16 hour charge.
Temperature Range:	0 °C to 45 °C (32 °F to 113 °F) Note: Delivery of high viscosity fluids at low temperatures is not recommended.
Keypad:	Elastomeric type, with tactile feedback.
Construction:	High-impact plastic case with removable elastomeric protective bumpers. Water resistant.

M E M O R A N D U M O F T E L E P H O N E C O N V E R S A T I O N

Date: March 21, 1994

Between: Nicole Wolanski, Biomedical Engineer
DGRD/GHDB, HFZ-410

And: Tamima Itani, Ph.D., Program Manager, Regulatory Affairs,
Baxter Healthcare Corp

RE: K940147

Today I spoke with Dr. Itani and asked the following questions about the Auto Syringe AS40A Infusion Pump:

1. Does your pump meet the AAMI ID26-1992 Infusion Device Standard?
2. Provide a statement with regard to the changes that have been made to the software since the clearance of K903343.
3. Specify a type or brand of syringe to be used with this pump.


Nicole L. Wolanski



Baxter

March 11, 1994

Ms. Nicole Wolanski
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center, HFZ-401
1390 Piccard Drive
Rockville, MD 20857

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15 MAR 94 13 41
FDA/CDRH/ODE/DMO

Re: 510(k) K940147

Blood Infusion Indication for Auto Syringe® AS40A Infusion Pump

Attachments

Via FAX: (301) 594-2358

(hard copy will follow via Federal Express)

Dear Ms. Wolanski:

I am providing additional information as requested by you in our telephone conversation on March 10, 1994. Your questions are repeated in bold.

Does the new indication for infusion of whole blood and packed red blood cells extend to the neonatal and pediatric populations? If yes, modify the labeling to be more specific.

The new indication for infusion of whole blood and packed red blood cells includes the neonatal and pediatric populations. The labeling has been modified to include these populations, and is attached.

Are there any instances in which adults would be infused 1 to 60 ccs of blood via a syringe infusion pump?

There are rare instances, where, due to the hemodynamic state of the adult patient, it is desirable to infuse small volumes of blood at very low infusion rates.

af

Baxter

Typically, blood is infused from a blood bag by drip. Compare the delivery rates from gravity infusion and from infusion via a syringe infusion pump.

Typical drip infusions of blood involve containers that contain 250 to 300 ml of blood. The duration of the infusion may be as short as approximately 5 minutes in acute trauma situations, or a maximum of 4 hours (AABB recommendation¹, excerpt attached). This translates into a minimum rate of 600 ml/hr (250 ml over 5 minutes) and a maximum rate of approximately 75 ml/hr (300 ml over 4 hours). In comparison, the delivery rate range of the syringe infusion pump is from 0.01 ml/hr to 360 ml/hr, and the delivery rate range of our Flo-Gard® 6201 and 6301 volumetric infusion pumps, cleared under 510(k)s K915522 and K915523 respectively and indicated for the infusion of blood, is 1 ml/hr to 1999 ml/hr.

Is there any literature that discusses the use of syringe infusion pumps to infuse blood in the neonatal and pediatric populations?

There are several papers that discuss the use of *volumetric* infusion pumps for infusion of blood in neonates and infants, and several others that discuss the impact of needle gauge on infusion of blood during manual syringe infusion of blood (see references attached in original 510(k)). However, the new literature search we conducted on the use of syringe infusion pumps in pediatric and neonatal patients resulted in one paper only by Strauss et. al.² The paper describes the use of a syringe and syringe pump for dispensing precise quantities of blood to neonatal patients. The syringe pump used in the study was an Auto Syringe pump, although the model is not specified. The paper concludes that "unit dose dispensing offers a precise and convenient method to prepare small, accurately measured quantities of filtered, sterile, and quality blood products for neonatal patients."

The infusion of blood in neonates and infants with syringe infusion pumps appears to be accepted clinical practice as referenced in the AABB Technical Manual¹, and in "Neonatal-perinatal medicine: diseases of the fetus and infant"³ (excerpts attached).

¹ American Association of Blood Banks: Technical Manual. 11th Edition. pp. 420-422. 1993.

² "Sterility and quality of blood dispensed in syringes for infants." Strauss, R.G., G.F. Crawford, C. Elbert, A.M. Floss, and M. Liesch. Transfusion, 26: 163-166, 1986.

³ Neonatal-perinatal medicine: diseases of the fetus and infant. Edited by A.A. Fanaroff and R.J. Martin. C.V. Mosby Company. pp. 881-884. 1987.

Baxter

Additional information:

For the sake of completeness, I would like to notify you at this time that the labeling submitted in the 510(k) as "Current Labeling" will be modified soon. Baxter had been selling two versions of the AS40A Infusion Pump: one with an optional drug library feature, and one without. Since the submission of this 510(k), we have discontinued the sale of the version that contains the drug library feature, and will modify the operator's manual at the next printing to remove all reference to the drug library feature. The pump without the feature retains all its other functional characteristics and the removal of the feature in no way impacts the addition of the blood pumping indication.

If you have any questions during your review of these responses, please contact me at (708) 270-4013. Alternately, you may contact Marcia Marconi, Director, Regulatory Affairs, at (708) 270-4637.

Sincerely,



Tamima Itani, Ph.D.
Program Manager
Regulatory Affairs
(708) 270-4013
(708) 270-4668 (FAX)

MODIFIED
LABELING

Device Description

The AS40A Infusion Pump is designed to meet the fluid and drug delivery requirements of today's changing clinical environment. It provides for accurate continuous or intermittent infusion via intravenous (IV), intra-arterial (IA), epidural, or subcutaneous routes of administration.

The AS40A accepts standard disposable syringes from 1 mL to 60 mL in size. A numeric keypad simplifies programming and makes the pump easier to use. Safety and effectiveness are reinforced by pre-programmable bolus operation, titration of a dose without interruption of fluid flow, and easily understood alarm and alert messages.

The AS40A can be custom configured for the healthcare facility. This allows an institution or clinic to select those key features which meet specific requirements. Configurable options include: Drug Library feature, syringe manufacturer, automatic syringe size recognition, selectable infusion modes, maximum infusion rates, occlusion pressure sensitivity, and keypad auto lock. The selected options can be reviewed easily by the user and the chosen configuration can be changed to meet new or different requirements.

The AS40A can run on its internal rechargeable battery pack and can also be operated while attached to a battery charger.

The AS40A is supplied with a pole clamp and a built-in IV pole loop. The pump can also be used as a table-top unit.

This paragraph will change to read:

The AS40A Infusion Pump is designed to meet the fluid and drug delivery requirements of today's changing clinical environment. It provides for accurate infusion, continuous or intermittent, of intravenous solutions, drug solutions, and whole blood and packed red blood cells, to patients including patients in the neonatal and pediatric populations. The pump is indicated for infusion via the intravenous (IV), intra-arterial (IA), epidural or subcutaneous routes of administration.

REFERENCE ARTICLES

28

wave energy in a uniform and controlled manner.¹²²

✓ *Electromechanical Infusion Devices*

Mechanical pumps that facilitate infusion at controlled rates are useful especially for very slow rates of transfusion to pediatric or neonatal patients. When using these pumps for blood transfusion, the transfusionist must ensure that hemolysis does not occur. Some pumps use a mechanical screwdrive to advance the plunger of a syringe filled with blood; others use roller pumps or other forms of pressure applied to infusion tubing. Although some can be used with standard blood administration sets, most require plastic disposables supplied by the manufacturer. RBCs with high hematocrit and high viscosity are more likely to undergo hemolysis when infused under pressure. WB or RBCs diluted with saline have lower viscosities and are less likely to undergo hemolysis. The manufacturer should be consulted before transfusing RBCs with an infusion pump designed for use with crystalloid or colloid solutions. Studies with radiolabeled red cells and platelets administered through a pump showed no loss of in-vitro function or in-vivo recovery.¹²³

Filters

Blood and components must be administered through a filter designed to retain blood clots and other debris. Standard blood filters have a pore size of 170-260 microns and can trap large blood clots. Some administration sets for PCs or CRYO have filters incorporated in tubing suitable for syringe administration. Filters are not routinely necessary for infusion of commercially prepared plasma products such as albumin, but the manufacturer's instructions should be consulted for specific recommendations.

Microaggregate filters have an effective pore size of 20-40 microns and trap microaggregates composed of degenerating platelets, white cells and fibrin strands, which form in blood after 5 or more days of refrigerated storage. Microaggregates can pass through standard blood filters and are thought to accumulate in pulmonary capillaries after transfusion. Whether or not microaggregate debris causes pulmonary dysfunction following massive transfusion has been extensively debated.^{124,125} No published data support the routine use of microaggregate blood filters for low volume transfusions.¹²⁵ Some emergency room physicians, surgeons and anesthesiologists believe that the slow flow that results from use of these filters makes them inappropriate in settings requiring very rapid massive transfusion.¹²⁵ There have been reports of hemolysis induced by use of a pediatric microaggregate filter.¹²⁶ Leukocyte-adsorption blood filters are the most effective filters for removing donor leukocytes from RBCs and PCs. See "Leukocyte-Reduced Blood Components" earlier in this chapter.

Needles

Flow at high pressure through small lumen needles may damage red cells.^{127,128} For infusing WB or RBCs, an 18- or 19-gauge needle gives good flow rates without excessive discomfort to the patient. For patients with small veins, much smaller needles must be used. A thin-walled, 23-gauge "scalp vein" needle is useful for pediatric transfusions and for adults whose larger veins are inaccessible. Undiluted RBCs flow very slowly through a 23-gauge needle, but diluting the cells with saline may cause unwanted volume expansion. In such cases it may be desirable to separate the unit into aliquots, keeping part

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280 MAR 11 1994

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of it in the blood bank while the first portion is transfused.

Either steel needles or plastic catheters can be used for transfusions. Catheters are more comfortable if infusions are to continue for a long period of time, and are less likely to become dislodged or puncture the vessel wall. The risks of infection and of thrombophlebitis increase with the length of time a catheter remains in place. Each facility should establish policy for the maximal time a catheter may remain in a vein and should outline a surveillance procedure to be sure that catheters are maintained aseptically and changed as often as specified.

Compatible Fluids

AABB *Standards* is explicit in stating that no medication may be added to blood or components. Solutions intended for intravenous use may be added to blood or components or used in an administration set if they have been approved for this use by the FDA or if documentation exists that they are safe and efficacious when added to the component. Diluting RBCs to reduce viscosity is commonly performed and intravenous solutions are sometimes used to rinse cryoprecipitate out of the bag. If fluid is to be instilled into the blood or component container, however, 0.9% saline is the only acceptable fluid.

Standards, however, is not explicit about which fluids may come in contact with blood in infusion sets, stating only that there must be adequate evidence that they are safe and approved by the FDA for admixture with blood components. Lactated Ringer's solution, 5% dextrose in water and hypotonic sodium chloride solutions should not be used. The dextrose solution causes red cells to clump in the tubing and, more important, causes red cells to swell and hemo-

lyze as dextrose and associated water diffuse from the medium into the cells.¹²⁹

Lactated Ringer's solution contains enough ionized calcium (3 mEq/L) to overcome the anticoagulant effect of CPDA-1 and allow small clots to develop. When blood follows an electrolyte solution through administration tubing, 25% of the electrolyte solution remains in the tubing after 10 minutes, and 10% persists at 30 minutes.¹²⁹

Care During Transfusion

The transfusionist should remain with the patient for the first few minutes after the start of the infusion. Catastrophic events such as anaphylactic reactions usually become apparent after a very small volume enters the patient's circulation. After the first 15 minutes, the patient should be observed and the vital signs recorded and, if there are no significant changes, the rate of infusion can be increased to that specified in the clinical order. Patient-care personnel should observe the patient frequently throughout the transfusion.

Rate of Infusion

The desirable rate of infusion varies with the patient's clinical condition. For rapid infusion, external pressure devices make it possible to administer a unit of blood within a few minutes. These should only be used with a large-bore needle. External compression devices should be equipped with a pressure gauge, and the pressure exerted should not exceed 300 torr. Blood pressure cuffs are not suitable because they do not exert uniform pressure against all parts of the bag, and irregularly applied pressure may cause the bag to leak.

While there are no experimental or clinical data to support a specific temporal restriction, the *Circular of Information* published by the AABB, the ARC and the

{ CCBC gives 4 hours as the maximal time permitted for an infusion. The *recommended time* for a routine transfusion should not be confused with the maximal time permitted for a transfusion.

There are also no definite rules for the length of time an administration set or filter may remain in use. A reasonable maximal time limit for use of a blood filter is 6 hours. Filters trap clumped cells, cellular debris and coagulated protein, resulting in a high protein concentration at the filter surface. If bacteria are present, the combination of room temperature incubation and high protein concentration could allow the bacteria to multiply on the filter more rapidly than they would in refrigerated blood. Accumulated material also slows the rate of flow. Standard 170-240 micron filters can ordinarily be used for two to four units of blood but filters that have remained at room temperature for prolonged periods should not be reused.

If blood flows more slowly than is desired, the filter or the needle may be obstructed, or the component may simply be too viscous for rapid flow through the administration set. Steps to investigate and correct the problem include the following:

1. Elevate the blood container to increase hydrostatic pressure.
2. Check the patency of the needle.
3. Examine the filter of the administration set for excessive debris.
4. If RBCs are flowing too slowly, and there is an order permitting addition of saline, add 50-100 mL normal saline.

Discontinuing the Transfusion

After each unit of blood has been infused, patient-care personnel should record the time, the volume and type of component given, the patient's condition and the identity of the person who

stopped the transfusion and observed the patient. Many transfusion services require that a copy of the completed transfusion form be returned to the transfusion service. There is no requirement to return the empty blood bag after uncomplicated transfusions. If bags are returned, proper biohazard precautions should be used. The patient should remain under observation for at least an hour after the transfusion is completed, and posttransfusion vital signs should be recorded according to the protocol established in the institution's procedures manual.

Pharmacologic Alternatives to Transfusion

Recombinant Growth Factors

Growth factors are low molecular weight proteins that regulate hematopoiesis by specific interaction with receptors found on bone marrow progenitor cells. The use of growth factors to stimulate endogenous blood cell production is an important alternative to the use of blood.¹³⁰

Erythropoietin

The clinical use of recombinant erythropoietin has revolutionized the transfusion support of patients with end-stage renal disease.¹³¹ Erythropoietin is also being investigated for the treatment of patients with the anemia of chronic disease, for postsurgical or intensive care unit patients or for patients who are receiving medications that suppress the bone marrow. The use of recombinant erythropoietin in the setting of preoperative autologous blood donation is discussed in Chapter 20.

MAR 11 1994

30

Sterility and quality of blood dispensed in syringes for infants

R. G. STRAUSS, G. F. CRAWFORD, C. ELBERT, A. M. FLOSS, AND M. LIESCH

A unit-dose system was designed to dispense precise quantities of blood in a form ready for immediate transfusion into neonatal patients. The principles were similar to those used by pharmacies to dispense individual doses of drugs. In the blood center, the precise volume of blood ordered for a neonatal patient was aspirated through a microaggregate filter into a labeled plastic syringe for dispensing to the nursery in a correspondingly labeled zip-lock plastic bag. In the nursery, the premeasured and prefiltered blood was ready for immediate infusion, and the syringe was attached directly to a mechanical infusion pump. Several experiments were performed to ensure sterility and quality of whole blood dispensed by this system. Over 300 aerobic and anaerobic cultures were performed, and it was concluded that the extra handling required to prepare syringes of blood did not lead to bacterial contamination. In addition, the quality of whole blood was maintained, for at least 6 hours, equally well in syringes as it was in blood bags stored under standard blood bank conditions when assessed by hematocrit, blood pH, and measurements of plasma potassium, glucose, lactic dehydrogenase, and free hemoglobin. Thus, unit dose dispensing offers a precise and convenient method to prepare small, accurately measured quantities of filtered, sterile, and quality blood products for neonatal patients. **TRANSFUSION** 1986;26:163-166.

SUPPLYING BLOOD PRODUCTS for neonatal patients, particularly those with prematurity, creates problems for blood centers. Tiny volumes of fresh blood are required frequently, and at times, special requests are made by neonatologists for blood products that are seronegative for cytomegalovirus, irradiated or filtered through microaggregate filters. Thus, it may be difficult to locate appropriate units quickly and to minimize wastage. To serve the nurseries at the University of Iowa Hospitals, a unit-dose system was designed for dispensing small volumes of premeasured and prefiltered blood in syringes, when ordered for designated neonatal patients. Using this system, a single unit of blood can supply syringes of blood for several patients.

Undoubtedly, other institutions use similar systems. However, we have been unable to find documentation that blood dispensed in this fashion is sterile and of satisfactory quality. Accordingly, before adopting this technique for general day-to-day use, quality control studies were performed, and the results are reported to serve as a basis for transfusion practice.

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Materials and Methods

Materials

Sterility and quality control studies in this report were done using whole blood to be certain that adequate quantities of plasma would be available for testing. Results of whole blood studies may not necessarily apply to blood components. It is likely that sterility results would be appropriate for all blood products, but the quality of individual blood components may vary and should be assessed separately. Blood was drawn into blood bags containing citrate-phosphate-dextrose-adenine (CPDA-1, Cutter Biological Laboratories, Inc., Berkeley, CA). Microaggregate filters (40 μ) were obtained commercially (Pall Biomedical Products Corporation, East Hills, NY); sample site couplers from Fenwal Laboratories, Deerfield, IL. Syringes (20 ml) also were obtained commercially (Luer-Lok, Becton Dickinson and Company, Rutherford, NJ). Syringes were attached to auto syringe mechanical pumps (Auto Syringe, Inc., Hooksett, NH) for infusion.

Unit-dose method for dispensing blood products

An inventory of fresh (up to 5 days of age) type O, Rh(D)-positive and -negative blood of known cytomegalovirus serology was maintained to satisfy demands of the nursery. Each 450-ml unit was collected in quadruple blood bags and then subdivided into three 150-ml aliquots to permit entering each aliquot separately in sequence. When a request for blood was received, the volume requested was aspirated from the satellite bag through a microaggregate filter and sample-site coupler (that had been punctured with a disposable needle) into a 20-ml labeled syringe (Fig. 1). The disposable needle was discarded, and the syringe was sealed with the cap and dispensed to the nursery in a zip-lock bag labeled to agree with the syringe (Fig. 2). A second identically labeled

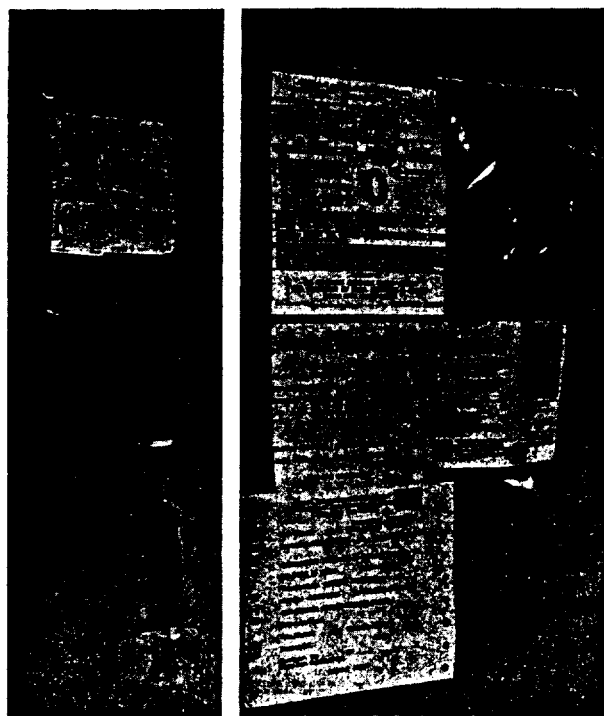


FIG. 1 (left). Aspiration via a disposable needle of the requested volume of blood from the primary blood bag, through the microaggregate filter and sample site coupler into the labeled syringe. FIG. 2 (right). The labeled syringe within the correspondingly labeled zip-lock plastic bag ready for dispensing to the nursery.

syringe was dispensed simultaneously if the requested volume for the single transfusion was 20 to 40 ml. Upon arrival in the nursery, the syringe was attached to the auto-syringe infusion pump for complete infusion within 6 hours of the time that it was filled in the blood dispensary.¹ Although the blood was filtered prior to release from the blood center, some neonatologists infused the final product through an additional filter (Blood Component Infusion Set, 4C2223, Fenwal Laboratories, Deerfield, IL). Approximately 3 ml of extra blood was ordered to fill this extra tubing. No additional volumes of blood were needed in the nursery since the blood was measured, filtered, and made ready for transfusion before dispensing.

The principles of this technique are similar to those of the unit-dose concept employed by pharmacies for dispensing drugs to designated patients. The primary unit (450 ml) can supply blood for several infants by being subdivided into the three satellite bags (150 ml each). Once a single satellite bag was entered with the microaggregate filter and sample-site coupler (Fig. 1), it was scheduled to outdate in 24 hours.¹ The entire set-up was stored at 4°C in the blood center. The original filter and coupler remained in place throughout this interval, and the coupler was cleaned with 70 percent isopropyl alcohol prior to repeat puncture with a new disposable needle to fill subsequent syringes. Generally, three to five neonatal transfusion orders can be filled from each satellite bag. Thus, a single primary blood unit might serve 15 neonatal patients. Each order was assigned a separate identification number (Typenex Blood Recipient identification bands, Fenwal).

Methods to assess sterility of unit-dose blood dispensed in syringes

Ten units of blood were entered with the spike tip of the microaggregate filter, and blood was aspirated through the filter, coupler, and needle into a syringe as described (Fig. 1). Five blood bags with attached filters and coupler sites, plus the five respective syringes of blood, were stored in a blood refrigerator at 4°C for 48 hours. Similarly, the other five sets of bags, filters, couplers, and syringes of blood were held at 22°C to simulate the temperature of hospital areas (blood bank, nurses station, nursery cribside table, etc.) where syringes of blood might reside prior to and during infusion. The lower temperatures (4 and 22°C) were considered to be more suitable than 37°C for detecting the mesophilic and psychrophilic bacteria that frequently contaminate blood products.² After 0, 3, 8, 24, and 48 hours of storage, separate samples were taken from each primary blood bag, filter and coupler, and from each syringe. A total of 150 samples were taken: three sites (X) 10 sets (X) five time intervals. Each sample was inoculated into thioglycollate broth and cultured under both aerobic and anaerobic conditions. Thus, a total of 300 culture results were available.

Although 4 and 22°C were selected for study, it was recognized that syringes of blood may be exposed to 37°C if placed inside incubators for transfusion. To be certain that our culturing techniques were able to detect both cold-growing organisms and pathogens that prefer body temperature, blood bags, filters-couplers, and syringes that had been stored at 4 and 22°C were sampled serially over a 48-hour interval. This time was well beyond the 6-hour outdate and sufficient to permit adequate growth, even at relatively low temperature, of organisms that grow well at body temperature. In addition, 8 units of whole blood were intentionally inoculated with approximately 200 colony forming units of *Staphylococcus aureus* (final concentration was one organism per each 2.2 ml whole blood). Immediately after inoculation and mixing, the primary bags were entered with filters, couplers and needles, and syringes were filled as described earlier. Blood bags, filters-couplers, and syringes were sampled after 0, 3, 8, 24, and 48 hours storage at both 4 and 22°C, and heavy growth of staphylococci were found in every culture.

Methods to assess quality of unit-dose blood dispensed in syringes

Ten units of whole blood (5 days of age) were entered with microaggregate filters and couplers. Samples were taken from the primary blood bags to establish baseline (0 hr) laboratory values, and additional blood was immediately aspirated through the filter-coupler and disposable needle into paired syringes. One syringe was stored with the primary bag under standard conditions in the blood bank refrigerator at 4°C; the other syringe was held at 22°C to simulate room temperature. After storage for 3, 6, and 24 hours, the primary bags and syringes were mixed thoroughly, and samples were taken for measurements of hematocrit, blood pH and plasma potassium, lactic dehydrogenase, free hemoglobin, and glucose.

Statistical methods to assess quality of blood in syringes

Initial baseline values, obtained from the primary 5-day-old blood bags at 0 hour, were compared to values obtained at each time interval sampled. For example, 0-hour baseline

values (primary blood bags) were compared to values obtained after 3-hour storage in primary bags at 4°C, and after similar storage in syringes at either 4 or 22°C. Differences were detected by analysis of variance, and the magnitude of differences was quantitated using Tukey's test.

Results

Sterility of multidose blood units and blood dispensed in syringes

Sterility was maintained at all culture sites (blood bags, filters and couplers, and syringes) for 24 hours after blood was aspirated from primary bags into syringes, when blood was held at either 4 or 22°C. Sixty cultures were taken (three sites [X] 10 sets [X] aerobic and anaerobic) 48 hours after syringes were filled, and a few colonies of bacteria were recovered from three syringes (one held at 4°C and two at 22°C). The three positive cultures yielded *Staphylococcus epidermis*, alpha-hemolytic streptococcus, and a diphtheroid. Thus, three of the total 300 cultures yielded an organism, and then only after an unrealistically long interval after the syringe was filled from the primary bag. As described in the methods section, the identical culturing method detected heavy growth of *Staphylococcus aureus* in 100 percent of cultures obtained from primary units, filters-couplers, and syringes after blood units were intentionally inoculated with small numbers of organisms.

As an additional study to test possible contamination under day-to-day, routine working conditions, aliquots were taken from 43 syringes actually dispensed to the nursery. The aliquots were held at 22°C for 24 hours to permit bacterial proliferation to occur prior to culturing. Cultures of all 43 aliquots were sterile.

Quality of blood dispensed in syringes

Results are presented in Table 1. Baseline values (primary unit zero hour) were as expected for whole blood that was 5 days old.³ Quality of the blood did not deteriorate throughout 6 hours of storage under any of the conditions (blood bags at 4°C and syringes at either 4 or 22°C). Moreover, values remained similar to baseline throughout 24 hours of storage under all conditions except for a decrease ($p < 0.05$) both of pH and glucose in syringes held for 24 hours at 4°C (Table 1).

Data also were analyzed by comparing all types of storage with others at every time interval sampled (e.g., pH of blood after 3-hr storage in blood bag at 4°C, versus pH of blood after 3-hr storage in syringe at 4°C, versus that in syringe after 3 hrs at 22°C). Differences were detected by analysis of variance, and the significance of differences was assessed using Dunnett's test. The only difference observed was the same significant decrease in pH and glucose after 24-hour storage in the syringe at 4°C that was detected in the previous analysis. Thus, the quality of whole blood held in syringes for at least 6 hours at either 4 or 22°C was comparable to that maintained in blood bags held under standard blood bank conditions at 4°C.

Discussion

A unit-dose system was designed to dispense blood for individual neonatal patients, and studies were performed to establish the sterility and quality of blood provided. Precise volumes of blood, as ordered for designated patients, were aspirated through micro-aggregate filters into labeled plastic syringes for dispensing in correspondingly labeled zip-lock plastic bags. Because blood was premeasured and prefiltered, it was ready for immediate transfusion. Accordingly, syringes were attached promptly to mechanical infusion pumps upon arrival in the nursery for direct infusion. It could be debated as to whether filtration with microaggregate devices was necessary,⁴ and this step could be eliminated if another type of blood filter was used instead at the time of infusion.⁵

Extensive microbiological studies indicated that the extra handling required to prepare syringes was not likely to lead to bacterial contamination. In addition, the quality of whole blood was maintained in syringes equally as well as it was in blood bags stored under standard blood bank conditions for at least 6 hours. Although the exact limit of storage time in syringes was not identified by current studies, it seems reasonable to prepare the syringes immediately before

Table 1. Quality control values (mean \pm SEM) of whole blood units ($n=10$) stored for 24 hours under standard conditions (blood bags at 4°C) or in syringes either at 4°C or room temperature (approximately 22°C)

Storage (hr)	Hematocrit (%)	pH	Potassium (mEq/l)	LDH Units	Plasma-free Hemoglobin (mg/dl)	Glucose (mg/dl)
Blood bag (4°C)						
0	37 \pm 2.3	7.06 \pm 0.03	9.6 \pm 0.8	226 \pm 37	13 \pm 2.3	409 \pm 6.8
3	39 \pm 2.7	7.09 \pm 0.02	9.5 \pm 0.8	249 \pm 40	15 \pm 2.4	403 \pm 4.4
6	36 \pm 2.4	7.06 \pm 0.02	9.6 \pm 0.8	258 \pm 44	15 \pm 3.4	404 \pm 7.1
24	36 \pm 2.7	7.05 \pm 0.03	10.4 \pm 0.8	291 \pm 48	19 \pm 5.1	394 \pm 7.7
Syringe (4°C)						
3	40 \pm 1.7	7.08 \pm 0.02	9.2 \pm 0.8	230 \pm 41	16 \pm 2.0	396 \pm 5.0
6	38 \pm 1.3	7.02 \pm 0.02	9.3 \pm 0.8	245 \pm 41	15 \pm 1.9	393 \pm 10.0
24	37 \pm 1.6	6.8 \pm 0.02*	9.4 \pm 0.7	290 \pm 39	17 \pm 2.8	334 \pm 5.6*
Syringe (22°C)						
3	36 \pm 1.3	7.06 \pm 0.02	9.8 \pm 0.7	231 \pm 39	13 \pm 1.9	401 \pm 4.6
6	37 \pm 0.9	7.06 \pm 0.02	10.1 \pm 0.7	243 \pm 38	14 \pm 1.9	407 \pm 8.4
24	36 \pm 2.5	7.05 \pm 0.02	11.3 \pm 0.7	259 \pm 42	14 \pm 2.1	396 \pm 6.5

* Significantly ($p < 0.05$) lower than initial baseline values of blood bag at zero hour.

MAR 11 1994

28 10

transfusion and to complete the entire transfusion as quickly as tolerated by the neonatal patient. Our current outdate is 6 hours after the syringe is filled.

It should be noted that this study dealt only with whole blood transfusion. It is likely that the results of sterility testing would apply to all blood products. Although this technique can be used easily to dispense packed red cells, platelet concentrates, fresh-frozen plasma, cryoprecipitate, and granulocyte concentrates, the quality of these products dispensed in this fashion is unknown. Therefore, blood products other than whole blood should not be dispensed in syringes until appropriate quality control studies are completed to document that they are functional and safe.

Acknowledgments

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Announcement

10th INTERNATIONAL CONVOCATION ON IMMUNOLOGY

Vaccines: New Concepts and Developments

The Ernest Witebsky Center for Immunology will present this symposium in its regular biennial series at the Hyatt Regency Buffalo Hotel, Buffalo, New York, on July 14-17, 1986, following the VIth International Congress of Immunology in Toronto, Canada, which is only 100 miles distant. Closed plenary sessions will focus on the following topics: Conceptual Basis of Antigens; Antigen Identification and Purification; Host Response; Production of Vaccines by Recombinant DNA Techniques; Idiotypic Vaccines; and Human and Veterinary Vaccines. Open poster sessions for free contributions on the theme will be offered. For further information, contact Dr. James F. Mohn, Director, The Ernest Witebsky Center for Immunology, 210 Sherman Hall, State University of New York at Buffalo, Buffalo, NY 14214 or call (716) 831-2848.

36
MAR 11 1986

NEONATAL-PERINATAL MEDICINE

Diseases of the Fetus and Infant

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MAR 11 1994

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in pythemic, hyperviscous neonates is congenital, at least partly because the prognosis for such depends greatly on the etiology. There is general agreement, however, that all newborns with a venous hematocrit exceeding 70%, even without symptoms, should be treated to reduce the hematocrit to at least 60%. FFP, plasma protein fraction USP (Plasmaplex), 5% albumin, and saline have been used as replacement fluids for the whole blood withdrawn. Albumin solutions are preferred to plasma because the risks of transfusion-transmitted infections associated with plasma, especially hepatitis and AIDS, are eliminated. The volume of exchange required can be calculated using the following formula:

$$\text{Volume of exchange (ml)} = \frac{\text{Blood volume} \times (\text{Observed hematocrit} - \text{Desired hematocrit})}{\text{Observed hematocrit}}$$

To correct severe anemia, packed RBCs are used as the replacement fluid for the whole blood withdrawn. The formula used to calculate the volume required for exchange is similar to the one just given; however, the hematocrit of the unit of RBCs used must be taken into account. RBCs usually have a hematocrit that approximates 70%; thus the formula:

$$\text{Volume of exchange} = \frac{\text{Blood volume} \times (\text{Desired hematocrit} - \text{Observed hematocrit})}{70\% - \text{Observed hematocrit}}$$

This formula is based on the assumption that the rise in hematocrit is a linear function of the volume of blood exchanged. The incremental change in hematocrit progressively diminishes throughout the exchange. This formula therefore may slightly underestimate the actual volume of exchange required to achieve the desired hematocrit.

The technique of partial exchange transfusion is similar to that used to accomplish a larger volume exchange. A continuous methodology is most often used, and aliquots of 5 ml/kg or less should be used for each withdrawal and infusion.

Replacement transfusions blood cell transfusions

Indications. Despite observations that (1) ill neonates as a group are more likely to be transfused than any other hospitalized patients and (2) RBCs are the most frequently transfused blood component in neonates, no uniformly accepted criteria exist for the transfusion of premature or term infants. This is partly because of the difficulty in measuring all the parameters that determine oxygen availability, oxygen delivery, and oxygen need in these patients.

Most RBC transfusions in newborns are administered under one of two circumstances. The first and most common indication is the replacement of acute blood loss resulting from hemorrhage or more often from iatrogenic measures required for laboratory testing and monitoring. The amount of blood drawn for testing has been variously estimated between 2% and 8% of the infant's blood volume per 24 hours spent in neonatal intensive care, despite the use of microanalytic techniques. A portion of this blood loss is "hidden loss," that volume of blood lost on cotton swabs or in the dead spaces of tubing or butterfly sets used to draw blood samples. Although neonates are capable of RBC production, their marrow response to anemia is slow compared to a normal adult. Thus the usual approach is to replace iatrogenic blood losses prophylactically rather than to attempt to determine whether an infant can physiologically tolerate the added insult of a falling hematocrit and some hypovolemia. The removal of 5% to 10% of an infant's blood volume over a short period necessitates blood replacement, particularly in an already compromised, sick neonate in whom symptoms of anemia may be difficult to recognize.

The second typical indication for neonatal RBC transfusion is correction of anemia, a determination that must be made by careful clinical assessment of the infant, the laboratory values (hematocrit and reticulocyte count), and other potential compensatory mechanisms such as the increase in intracellular 2,3-DPG, which normally occurs during the "physiologic" anemia of infancy. Signs and symptoms traditionally associated with anemia in a neonate include tachypnea, tachycardia, pallor, lethargy, apnea, and poor weight gain. However, no linear correlation exists between the hemoglobin concentration alone and the presence or absence of the clinical signs of anemia (tachypnea, tachycardia). The correlation that does exist is between the signs and symptoms of anemia and the *available oxygen*, a function of the hemoglobin concentration and the position of the oxygen-hemoglobin dissociation curve. Thus some neonates appear clinically anemic despite measured hemoglobin concentrations in the normal range for age. In contrast, infants undergoing exchange transfusion in the immediate newborn period are more likely to tolerate lower levels of hemoglobin well than are similarly aged infants with no exchange transfusion. Replacement of RBCs containing adult hemoglobin for those containing fetal hemoglobin in these infants results in more available oxygen and less stimulus for reticulocyte production at any given hemoglobin level.

Representative criteria for RBC transfusion of infants with and without respiratory distress are listed in the boxed material. Infants with continued respiratory distress are transfused more aggressively. Preterm infants

Criteria for replacement transfusion in the high-risk infant

WITH RESPIRATORY DISTRESS, TRANSFUSION SHOULD BE GIVEN WHEN:

The hematocrit is less than 40%.

Hypovolemia is present, as judged by (1) pallor, (2) pulse rate greater than 160/minute, or (3) systolic blood pressure less than 50 mm Hg (birth weight greater than 1,000 g).

Greater than 10% of the blood volume has been removed within 48 hours and the hematocrit is less than 45%.

IN THE ABSENCE OF RESPIRATORY DISTRESS, TRANSFUSIONS SHOULD BE GIVEN WHEN:

The hematocrit is less than 30% in the first week of life.

The pulse rate is greater than 160/minute, the respiratory rate is greater than 60/minute, or roentgenograms reveal cardiomegaly.

Modified from Lubin, B.: Clin. Haematol. 7:19, 1978.

have been shown to have improvements in weight gain associated with a decrease in oxygen consumption and metabolic rate during the week following a RBC transfusion (10 ml/kg), as compared to these same parameters measured before the transfusion. In the treatment of symptomatic anemia, at least 10 ml of RBCs/kg is a typically used dosage.

Red cell preparations. The optimal RBC product for neonatal transfusion is a small sterile aliquot of readily available compatible RBCs with a hematocrit of approximately 65%; well-preserved 2,3-DPG; minimal biochemical changes, particularly a relatively high pH and low supernatant potassium concentration; minimal risk of transmitting infection; and the option to obtain several such aliquots from the same blood donor. Several methods have been developed that address these particular needs.

Quadruple packs. Whole blood collected into CPDA-1 anticoagulant/preservative solution and stored less than 5 to 7 days meets the biochemical criteria for transfusion to neonates. In a quadruple pack, a primary blood collection bag with three integrally connected satellite bags, plasma can be removed into one satellite bag, and the remaining RBCs with a usual hematocrit approximating 70% can be divided into the other three bags. Each bag will contain one third of a unit of RBCs, about 85 ml. Since all these manipulations are performed without entering the quad pack system, each of the one-third units retains its normal shelf life.

Each of the 85 ml aliquots may be further apportioned into two, three, or four pediatric transfer bags, depending on the volume requested for each infant's transfusion.

Each of the original one-third units should be entered and appropriately apportioned at the time of use, since they must be transfused within 24 hours of entering. Using this system, several infants can be transfused from a single blood donation. In addition, an infant requiring daily replacement transfusions can receive RBCs, with a maximum pretransfusion storage period of 5 days, from the same blood donor unit on 3 successive days. Minimizing donor exposure is an important way to decrease the risk of transfusion-transmitted infections. Good communication between the nursery and the transfusion service is essential to optimize this blood utilization protocol.

Unit-dose system. Distribution of the precise volume of prefiltered RBCs in syringes is a useful technique in nurseries where several infants receive one or more small volume transfusions per day with a syringe mechanical infusion pump. Whole blood can be collected into a multiple-pack system as just noted and RBCs prepared. A resealable injection site coupler inserted into an access port of the blood bag permits repeated entry into that unit or partial unit over 24 hours. Whenever RBCs are needed, the volume requested is aspirated into a syringe through a needle inserted into the injection site and an appropriate blood filter, usually a neonatal microaggregate filter. A sterile cap is used to cover the filled syringe, and appropriate identifying labels are applied to the syringe. Using this system minimizes wastage of blood through the flexibility in the volume of the component that can be prepared. These small syringe aliquots are sterile and show no deterioration in the quality of the component, as measured by hematocrit, pH, supernatant potassium concentration, lactate dehydrogenase (LDH) level, plasma free hemoglobin, or glucose during the six hours following dispensing. Alternatively, if a blood bank-monitored refrigerator is maintained in the neonatal intensive care unit, partial RBC units may be released daily to the nursery, labeled with identification of the infant or infants for whom each unit is intended. When a transfusion is ordered, nursing personnel who will administer the transfusion follow the same procedure as just described to obtain the precise amount of blood required. This also ensures that many small transfusions to a single neonate within 24 hours will be from the same donor unit.

Half-unit donations. Approximately 225 ml of blood can be collected into a triple-pack system after adjusting the volume of anticoagulant. Removal of the plasma into one of the satellite bags results in two aliquots of RBCs, each with a volume about 60 ml, appropriate for neonatal transfusion. This practice provides an opportunity to use healthy blood donors who do not meet the 50 kg minimum weight requirement for donation of a whole unit of blood. This methodology may be important in ex-

g the blood donor pool, thereby ensuring the availability of relatively fresh RBCs for neonates.

Individual small units. A full unit of whole blood is composed of the premeasured anticoagulant/preservative solution plus 450 ml \pm 10% of donor blood. If the maximum 495 ml is collected into a bag with one satellite bag, 30 to 60 ml can be removed into the satellite bag for neonatal use, and the remainder is enough to serve as an ordinary whole unit. Although this technique could produce many small aliquots of relatively fresh blood without the need to recruit new blood donors, the inability to provide multiple transfusions for a patient from the same blood donor unit is a distinct disadvantage.

Saline-washed red blood cells. Saline-washed RBCs are an alternative product for neonatal use. Two pediatric-sized units of approximately 135 ml each can be produced from a single unit of whole blood using an automated blood cell processor. Both pediatric units have only a 24-hour shelf life after washing. Aliquots can be obtained for neonatal transfusion using either multiple pediatric transfer bags or syringes, as already described. Saline-washed RBC units have a significantly reduced supernatant potassium concentration, essentially no citrate, few leukocytes, and less than 0.2% of the original plasma proteins. Whole blood units less than 1 week from collection are still required to ensure adequate levels of 2,3-DPG.

Frozen deglycerolized red blood cell systems. Small volumes of deglycerolized RBCs can be prepared from a unit of RBCs that are glycerolized in a standard fashion, separated into three equal aliquots, and frozen. When thawed and deglycerolized for transfusion, each aliquot contains 60 to 70 ml of RBCs, with an average hematocrit of 75%. Each aliquot may be thawed as needed but must be transfused within 24 hours of thawing and deglycerolization. A single donor unit may thus be used for a single infant on 3 separate days. Each aliquot could also be further divided into smaller-volume portions for transfusion to several infants within a 24-hour period. FDCs have 2,3-DPG levels equivalent to those in freshly drawn blood, a markedly lower supernatant potassium concentration, very few leukocytes and platelets, and only minute amounts of plasma proteins and anticoagulant. FDCs carry a low risk of CMV transmission. They are, however, generally more expensive and require more preparation time than liquid-stored RBCs.

RBCs nearing their expiration date can be biochemically modified before being glycerolized and frozen as just described. These "rejuvenated" RBC units have improved oxygen transport function at the time of transfusion; 2,3-DPG levels are 150% of normal. The ability to rejuvenate RBCs could decrease the wastage of blood in providing RBCs especially suited for neonates.

Walking donor programs. On-call blood donors, usually

hospital personnel, have sometimes been used to provide small volumes of heparinized whole blood, drawn into syringes as needed for neonatal transfusion before the development of alternative methods such as those already described. This methodology is listed here to discourage its use by highlighting its disadvantages:

1. No pretransfusion compatibility testing
2. No pretransfusion screening for hepatitis, AIDS, or CMV
3. Suboptimal donor health history screening
4. No pretransfusion donor and patient samples available to evaluate adverse reactions
5. Generally poor transfusion records
6. Risk of overheparinization of the blood, causing coagulopathy or hemorrhage in the neonate
7. Potential bacterial contamination of the blood through faulty phlebotomy technique
8. Potentially increased risk of hepatitis transmission by using untested blood donors who work in a high-risk hospital environment
9. An increased burden on the nursery staff, who must assume the responsibility for donor recruitment, phlebotomy, and any storage of the blood

Technical aspects. Careful attention to the technical aspects of RBC transfusion is more important to achieving a successful transfusion than is usually appreciated. This is particularly true in neonates, for whom small volumes of RBCs blood cells are variously manipulated in an attempt to meet the perceived needs of the neonatal transfusion recipient more adequately. Because of the small size and relative immaturity of the newborn, seemingly insignificant changes in the RBC component may become major problems in the infant.

Filters. All blood components must be filtered before transfusion. The use of a standard 170 μ m blood filter is sufficient for most RBC-containing components in newborns. Microaggregate filters (pore size 10 to 20 μ m) with a small internal volume specifically for neonatal use are commercially available, but their value in routine usage is controversial. Microaggregates are the 20 to 120 μ m particles of nonviable granulocytes, platelets, and fibrin strands that progressively develop in RBC and whole blood units throughout the storage period. When neonates routinely receive blood stored less than 5 to 7 days, there should be little danger from microaggregates because very few of these particles exist in such fresh blood. If neonatal microaggregate filters are used, care must be taken to follow the manufacturer's instructions exactly. Most neonatal microaggregate filters are made to accommodate only a single, small-volume transfusion; these should not be used for larger transfusions, including exchange transfusion. If unusual resistance is encountered in aspiration of blood through a filter and no visible clots are seen within the RBC unit, the filter

should be changed. Two severe hemolytic reactions, one fatal, have been reported resulting from pretransfusion mechanical trauma to RBCs in a microaggregate filter. Measurable hemolysis, which increased as the rate of filtration decreased, has been observed with blood stored for as little as 1 day.

Needle size. For replacement transfusions of RBCs, the optimum needle or catheter size and the rate of infusion that minimize the risk of mechanical hemolysis are not clear. A substantial increment in hemolysis accompanies an increase in flow rate and a decrease in needle size (23- and 25-gauge needles) when 9-day-old RBCs are used. No significant hemolysis of fresh RBCs is noted with different needle gauges (21, 23, 25, 27) and various rates, suggesting that the small-caliber needles required in tiny preterm infants may be adequate for RBC transfusion when all other technical aspects of the transfusion have been optimized.

* **Infusion pumps.** Small-volume RBC transfusions are usually administered slowly using a mechanical infusion pump. Several varieties of pumps are commercially available. Some have been studied and found to be suitable for RBC transfusion, whereas others may not be suitable. Infusion pumps should be tested to determine that hemolysis does not occur before their use in RBC transfusion.

Warming of blood. No published studies address the safety or the consequences of slowly transfusing relatively cold, small-volume RBC aliquots to neonatal patients. Although traditionally considered to be unnecessary, small-volume RBC aliquots in syringes are often warmed before transfusion, presumably based on anecdotal experiences. Various warming techniques are in use. A syringe aliquot cannot be warmed in a conventional water bath because it is an open system and susceptible to spillage and contamination. The large dead space in conventional blood warmers precludes their use for these small volumes. A labeled syringe aliquot of RBCs placed inside the temperature-controlled Isolette of the intended neonatal recipient for 30 minutes before transfusion warms more rapidly than similar aliquots left at room temperature. However, the temperature of the blood inside the Isolette syringes does not reach the temperature set for the Isolette, even after 90 minutes. No evidence of RBC destruction is seen when syringes of RBCs are held for the maximum allowable duration of a transfusion (6 hours) in a 37° C warm air incubator. However, when syringes of RBCs are placed adjacent to a neonate under a radiant warmer, significant erythrocyte damage occurs, as evidenced by increased plasma-free hemoglobin, increased supernatant potassium concentration, and decreased pH. This erythrocyte damage is observed both when the radiant heater is operated at full power and when the infrared energy output is regulated

via skin temperature servocontrol. Excessive heating can be avoided and the RBC damage minimized by placing the syringes of blood on a stand beside the radiant warmer rather than directly under it or by shielding the syringe with aluminum foil. RBCs in syringes may be safely and effectively warmed before neonatal transfusion by placing the labeled syringe inside the infant's warm air Isolette. In contrast, when an infant who is being managed under a radiant warmer requires a transfusion, extreme caution must be used to place the syringe aliquot of RBCs beside, rather than under, the radiant warmer. If the syringe and infusion pump must be placed under the radiant warmer beside the infant for the transfusion, the RBCs should be shielded with aluminum foil to minimize hemolysis.

Fresh frozen plasma transfusions

Product definition. FFP is the anticoagulated fluid portion of one unit of blood that has been centrifuged, separated, and frozen solid within 6 hours of collection. FFP contains all the clotting factors including fibrinogen, fibronectin, γ -globulins, albumin, and other plasma proteins in the same concentration as they are present in the normal blood donor. None of the proteins is concentrated during preparation.

Other single-donor frozen plasma products are available in some regions of the United States. These differ only in that they were processed and frozen between 6 and 24 hours of the whole blood collection and therefore contain slightly lower concentrations of the labile plasma coagulation factors, factor V and factor VIII. The maximum expected loss of activity of these coagulation factors is 20% to 25%. Thus the indications for the various frozen plasma products are interchangeable, except for the treatment of severe factor V deficiency, in which FFP is the treatment of choice. The term FFP is used throughout the remainder of this section to refer to all single-donor frozen plasma products.

Indications. Few specific indications exist for the use of FFP in neonates; most indications are associated with correction of acquired or congenital coagulation factor deficiencies.

1. FFP is indicated as part of the replacement fluid in a two-volume exchange transfusion because of the anticipated coagulation factor deficiency that accompanies this procedure.
2. Hemorrhage secondary to vitamin K deficiency and the resultant decreased activity of the vitamin K-dependent coagulation factors—II (prothrombin), VII, IX, and X—is rare except in infants not given prophylaxis. An infant with severe vitamin K deficiency and bleeding should be treated with a single transfusion of FFP, 15 to 20 ml/kg, to supply the deficient factors quickly and to control the bleeding.

MAR 11 1994

16

MEMORANDUM OF TELEPHONE CONVERSATION

Date: March 10, 1994

Between: Nicole Wolanski, Biomedical Engineer
DGRD/GHDB, HFZ-410

And: Tamima Itani, Ph.D., Program Manager, Regulatory Affairs, Baxter

RE: K940147, Auto Syringe AS40A Infusion Pump

Today I called Dr. Itani and asked the following questions:

1. Does the new indication for infusion of whole blood and packed red blood cells extend to the neonatal and pediatric populations? If yes, please modify labeling to be more specific.
2. Are there any instances in which adults would be infused 1 to 60 ccs (the acceptable size range of syringes to be used with this pump) of blood via a syringe infusion pump?
3. Typically, blood is infused from a blood bag by drip. Compare the delivery rates from gravity infusion and from infusion via a syringe infusion pump.
4. Is there any literature that discusses the use of syringe infusion pumps to infuse blood in the neonatal and pediatric population?


Nicole L. Wolanski



Premarket Notification (510(k)) Checklist for Acceptance Decision

K 940147 Date DMC Received 1-11-94
 Device Trade Name: Auto Syringe AS 40A Infusion Pump
 Reason for 510(k) New indication for use
 Division/Branch: DG-RD/6HDP
 Administrative Reviewer Signature: [Signature] Date 2/4/94
 Supervisory Signature: [Signature] Date 2/4/94
 Did the firm request expedited review NO
 Did we grant expedited review ✓

accepted refuse to
accept
 See attached manufacturers checklist. = checklist is a duplicate to
 accept device.

[Signature]

Yes
Present
Omission Justified

No
Inadequate
Omitted

I. Critical Elements:		
A. Is the product a device?	<input type="checkbox"/>	<input type="checkbox"/>
B. Is the device exempt from 510(k) by regulation or policy?	<input type="checkbox"/>	<input type="checkbox"/>
C. Is device subject to review by CDRH?	<input type="checkbox"/>	<input type="checkbox"/>
D. (i) Are you aware that this device has been the subject of a previous NSE decision? (ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?	<input type="checkbox"/>	<input type="checkbox"/>
E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer.	<input type="checkbox"/>	<input type="checkbox"/>
(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/>	<input type="checkbox"/>

Yes Present Omission Justified

No Inadequate Omitted

<p>F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:</p>		
<p>1. Device trade or proprietary name</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>2. Device common or usual name or classification name</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>3. Establishment registration number (only applies if establishment is registered)</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>4. Class into which the device is classified under (21 CFR Parts 862 to 892)</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>5. Classification Panel</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>6. Action taken to comply with Section 514 of the Act</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)</p>	<input type="checkbox"/>	<input type="checkbox"/>

Yes
Present
Omission Justified

No
Inadequate
Omitted

8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	<input type="checkbox"/>	<input type="checkbox"/>
9. For class III devices only, a class III certification and a class III summary	<input type="checkbox"/>	<input type="checkbox"/>
10. Photographs of the device	<input type="checkbox"/>	<input type="checkbox"/>
11. Engineering drawings for the device with dimensions and tolerances	<input type="checkbox"/>	<input type="checkbox"/>
12. The marketed device(s) to which equivalence is claimed including labeling and description of the device	<input type="checkbox"/>	<input type="checkbox"/>
13. Statement of similarities and/or differences with marketed device(s)	<input type="checkbox"/>	<input type="checkbox"/>
14. Data to show consequences and effects of a modified device(s)	<input type="checkbox"/>	<input type="checkbox"/>
II. Additional Information that is necessary under 21 CFR 807.87(h):		
A. Submitter's name and address	<input type="checkbox"/>	<input type="checkbox"/>

Yes
Present
Omission Justified

No
Inadequate
Omitted

B. Contact person, telephone number and fax number	<input type="checkbox"/>	<input type="checkbox"/>
C. Representative/Consultant if applicable	<input type="checkbox"/>	<input type="checkbox"/>
D. Table of Contents with pagination	<input type="checkbox"/>	<input type="checkbox"/>
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	<input type="checkbox"/>	<input type="checkbox"/>
III. Additional Information that may be necessary under 21 CFR 807.87(h):		
A. Comparison table of the new device to the marketed device(s)	<input type="checkbox"/>	<input type="checkbox"/>
B. Action taken to comply with voluntary standards	<input type="checkbox"/>	<input type="checkbox"/>
C. Performance data		
marketed device		
bench testing	<input type="checkbox"/>	<input type="checkbox"/>
animal testing	<input type="checkbox"/>	<input type="checkbox"/>
clinical data	<input type="checkbox"/>	<input type="checkbox"/>

Yes
Present
Omission Justified

No
Inadequate
Omitted

new device			
bench testing	<input type="checkbox"/>		<input type="checkbox"/>
animal testing	<input type="checkbox"/>		<input type="checkbox"/>
clinical data	<input type="checkbox"/>		<input type="checkbox"/>
D. Sterilization information	<input type="checkbox"/>		<input type="checkbox"/>
E. Software information	<input type="checkbox"/>		<input type="checkbox"/>
F. Hardware information	<input type="checkbox"/>		<input type="checkbox"/>
G. If this 510(k) is for a kit, has the kit certification statement been provided?	<input type="checkbox"/>		<input type="checkbox"/>
H. Is this device subject to issues that have been addressed in specific guidance document(s)?	<input type="checkbox"/>		<input type="checkbox"/>
If yes, continue review with checklist from any appropriate guidance documents.			
If no, is 510(k) sufficiently complete to allow substantive review?			

Yes
Present
Omission Justified

No
Inadequate
Omitted

I. Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>
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SR

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

January 31, 1994

BAXTER CORP.
I.V. SYSTEMS DIVISION
ROUTE 120 AND WILSON ROAD
ROUND LAKE, IL 60073
ATTN: TAMIMA ITANI, PH.D.

510(k) Number: K940147
Received: 11-JAN-94
Product: AUTO SYRINGE
AS40A INFUSION
PUMP

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- o Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
510(k) Status Coordinator
Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, Maryland 20857 USA
Because of staff limitations, we cannot answer telephone status requests.
- o 510(k) status requests should include:
 - (1) submitter's name and mailing address;
 - (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

- (3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- o Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
 - (1) the branch to which the 510(k) has been assigned;
 - (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
 - (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

51


description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.



If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

A handwritten signature, likely of Marjorie Shulman, located in the bottom right corner of the page.

PREMARKET NOTIFICATION (510(k)) STATUS REQUEST

TO: 510(k) Status Coordinator
Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, MD 20857
USA
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

_____ fax
_____ mail

A. Sponsor Information:

1. Name of 510(k) sponsor: _____
2. Sponsor's mailing address: _____

B. Requester information:

1. Requester name: _____
2. Requester affiliation with sponsor: _____
3. Requester mailing address: _____

4. Request fax number (if applicable): _____
5. Requester telephone number: _____

C. 510(k) information:

1. Product name: _____
2. 510(k) number: _____
3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE): _____

Name of contact person identified on firm's 510(k) submission: _____

I certify that the above information is accurate and truthful to the best of my knowledge.

K940147

Baxter

January 7, 1994

FDA/CDRH/OD/DNC

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11 JAN 94 11 47

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center, HFZ-401
1390 Piccard Drive
Rockville, MD 20857

Re: 510(k) Premarket Notification
Blood Infusion Indication for Auto Syringe® AS40A Infusion Pump

Attachments

Dear Sir or Madam:

This is to notify you of the intention by Baxter Healthcare Corporation to expand the current indications of the Auto Syringe® AS40A Infusion Pump to include the infusion of whole blood and packed red blood cells (PRBC). The Auto Syringe® AS40A Infusion Pump received premarket clearance under K903343 on July 17, 1990 and under K911289 on March 14, 1991, for continuous or intermittent infusion of intravenous or drug solutions via intravenous, intra-arterial, epidural or subcutaneous routes of administration.

For your convenience, we have completed a copy of FDA's "Premarket Notification (510(k)) Checklist for Acceptance Decision¹", and attached it to this submission. We also explain how we reached a substantial equivalence conclusion, using FDA's logic flow chart entitled "510(k) "Substantial Equivalence" Decision-Making Process (Detailed)²." (SE Logic Flow Chart tab).

Classification Name: Infusion Pump

Common/Usual Name: Syringe Infusion pump

Proprietary Name: Auto Syringe® AS40A Infusion Pump

¹ Center for Devices and Radiological Health's Premarket Notification (510(k)) Refuse to Accept Policy, June 30, 1993

² FDA's Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program, June 30, 1986.



Manufacturer's Name, Site, Address and Establishment Registration

Number:

Baxter Healthcare Pte. Ltd.
2 Woodlands Industrial Park D
Singapore 25473
Establishment Registration Number: 9612057

Owner/Operator (firm headquarters) Address and Establishment

Registration Number:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015
Registration Number: 1417572

Classification: Class II in 21 CFR §880.5725, Infusion Pump (Panel 80, FRN)

Performance Standard: None promulgated under Section 514

Intended Use:

The pump can be used for continuous or intermittent infusion of intravenous or drug solutions via intravenous, intra-arterial, epidural or subcutaneous routes of administration; to deliver whole blood or packed red blood cells; or can be piggybacked into an ongoing I.V. line to automatically, precisely and economically deliver secondary solutions.

The only new indication is for the infusion of whole blood and packed red blood cells.

Technological Characteristics:

The method of operation, product design, and materials are identical to the currently marketed Auto Syringe® AS40A Infusion Pump. The addition of the blood pumping indication does not impact the current software or hardware configurations.



Performance Data:

Performance data applicable to the Auto Syringe® AS40A Infusion pump were obtained from a Baxter study, and from a study by Gibson³ and co-workers. The Baxter study was performed using an Auto Syringe® AS-5A Infusion Pump to pump undiluted whole blood, undiluted packed red blood cells, and diluted packed red blood cells. It appears in the attached document, **Auto Syringe® AS-5A Pump Hemolysis Evaluation**. The study by Gibson and co-workers was performed using an Auto Syringe® AS-2FH model, and is attached under **Referenced Articles**. The Auto-Syringe® AS-5A and AS-2FH Infusion Pumps both use the same pumping mechanism as the AS40A Infusion Pump, as described in the attached document (**Comparison between the Auto Syringe® AS-5A, AS-2FH, and AS40A Infusion Pumps**) and therefore the performance data presented here are applicable to the AS40A model.

The Baxter study demonstrated that under extreme testing conditions (undiluted packed red blood cells, micro-connector set), the syringe pump produced 0.102% hemolysis, or a plasma free-hemoglobin concentration of 54.9 ± 42.6 mg/dL (page 24 of **Auto Syringe® AS-5A Pump Hemolysis Evaluation**).

In the study by Gibson³ and co-workers, the syringe pump produced a plasma free-hemoglobin concentration of 8 ± 5 mg/dL in the case of whole blood, and 25 ± 4 mg/dL in the case of packed red blood cells.

While some investigators have suggested what levels of hemolysis might be clinically acceptable, it appears that such levels have not been absolutely established. A study by Veerman et al.⁴, which is included in the **Referenced Articles**, suggests that 0.3% (0 to 92.9 mg/dL) is within typical plasma hemoglobin values measured in 35 day stored whole blood and packed cells. Moss and Stauton⁵ (**Referenced Articles**) consider a hemolysis rate of 0.17%

³ "Effects of intravenous delivery systems on infused Red Blood Cells (RBC)." Gibson, JS, DL Leff, and RJ Roberts. American Journal of Hospital Pharmacy, 41, pp. 468-472, Mar 1984.

⁴ "Influence of two piston-type infusion pumps on hemolysis of infused red blood cells." Veerman, MW, RD Leff, and RJ Roberts. American Journal of Hospital Pharmacy, 42, Mar 1985: 626-628.

⁵ "Blood flow, needle size and hemolysis - Examining an old wife's tale." Moss, G., and C. Stauton. N. England J. Med., 1970, 282(17): 967.



to be "minimal". Eurenus et al.⁶ (**Referenced Articles**) evaluated that hemolysis values under 75 mg/dL plasma free hemoglobin are not considered to be of clinical significance in causing morbidity or mortality. Wilcox⁷ et al. and Gibson³ et al. (**Referenced Articles**) indicate that 0.2% hemolysis is a "tolerable" level of hemolysis during infusion.

Hemolysis rates of the Auto Syringe® Infusion Pumps are thus below generally acceptable clinical rates. The application and range of infusion rates for pumping blood products should be limited to the individual institution's guidelines, since no mutually agreed upon maximum hemolysis levels have been generally accepted by the medical community. Data should be evaluated by the individual institution for interpretation and application based upon their own policy. Baxter will make hemolysis data available to customers upon request.

Labeling/Promotional Material:

The pump is labeled for use for continuous or intermittent infusion of intravenous or drug solutions via intravenous, intra-arterial, epidural or subcutaneous routes of administration; to deliver blood products (whole blood and packed red blood cells); or can be piggybacked into an ongoing I.V. line to automatically, precisely and economically deliver secondary solutions.

The current version of the Operation Manual has been revised to include an indication for the delivery of whole blood and packed red blood cells. Current labeling is attached. The proposed change to the current labeling appears under **Proposed Labeling**.

Substantial Equivalence:

This product is substantially equivalent, for purposes of section 510(k) of the Federal Food, Drug and Cosmetic Act only, to our currently marketed Auto Syringe® AS40 pump, found to be substantially equivalent on November 21, 1990 (K903343). It is also equivalent, for purposes of section 510(k) of the Federal Food, Drug and Cosmetic Act only, to the Auto Syringe® AS-5A Infusion Pump, found to be substantially equivalent on February 7, 1978 (K782034); and to the Medfusion Model 2001 Syringe Infusion Pump (indicated for the continuous or intermittent infusion of blood), found to be

⁶ "Hemolysis in blood infused under pressure." Eurenus, S. and R.M. Smith. Anesthesiology, 1973, 39:650-651.

⁷ "Does transfusion using a syringe infusion pump and small-gauge needle cause hemolysis?" Wilcox, GJ, A. Barnes, and H. Modaniou. Transfusion, 21 (6), Nov. - Dec. 1981.



substantially equivalent on December 24, 1990 (K905029). A table comparing the Auto Syringe® AS40A Infusion Pump to the Medfusion Model 2001 Syringe Infusion Pump appears in the **Comparison Table** attachment. The operation of the Medfusion pump is described in the **Medfusion Operation Manual**. Finally, we also explain, under the **Flow Chart** attachment, how we reached a substantial equivalence conclusion, using FDA's logic flow chart entitled "510(k) "Substantial Equivalence" Decision-Making Process (Detailed)".

Summary of Safety and Effectiveness:

A summary of safety and effectiveness is attached.

If you have any questions during your review of this notification, please contact me at (708) 270-4013. Alternately, you may contact Marcia Marconi, Director, Regulatory Affairs, at (708) 270-4637.

Sincerely,

Tamima Itani, Ph.D.
Program Manager
Regulatory Affairs
(708) 270-4013
(708) 270-4668 (FAX)

Table of Contents

Table of Contents

Table of Contents

Cover Letter

Classification Name	1
Common/Usual Name	1
Proprietary Name	1
Manufacturing and Sterilization Location/Establishment	
Registration Number	2
Owner/Operator Number	2
Classification	2
Performance Standard	2
Intended Use	2
Technological Characteristics	2
Performance Data	3
Labeling/Promotional Material	4
Substantial Equivalence	4
Summary of Safety and Effectiveness	5

Attachments

Table of Contents	6
"Premarket Notification (510(k)) Checklist for Acceptance Decision"	8
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)	15
Auto Syringe® AS-5A Pump Hemolysis Evaluation	19
A comparison between the pumping mechanisms of the AS-5A, AS-2FH and AS40A Auto Syringe® Infusion Pumps.	50
Referenced articles	54
Current Labeling	68
Proposed Labeling	153
Comparison of Features between the Auto Syringe® AS40A Infusion Pump and the Medfusion 2001 Syringe Infusion Pump	155
Medfusion Model 2001 Syringe Infusion Pump Operations Manual	157
Summary of safety and effectiveness	237

62
7

Reviewer
checklist

510(k) Premarket Notification
Blood Infusion Indication for
Auto Syringe® AS40A Infusion Pump
January 7, 1994

Premarket Notification (510(k)) Checklist
for Acceptance Decision

Premarket Notification (510(k) Checklist for Acceptance Decision

K: _____ **Date DMC Received:** _____

Device Trade Name: Auto-Syringe® AS40A Infusion Pump
Reason for 510(k): Addition of New Indication: Infusion of Whole Blood and of Packed Red Blood Cells
Division/Branch: Division of General and Restorative Devices/General Hospital Devices Branch
Administrative Reviewer Signature: _____ **Date:** _____
Supervisory Signature: _____ **Date:** _____

	Yes Present Omission Justified	No Inadequate Omitted
--	--------------------------------------	-----------------------------

I. Critical Elements		
A. Is the product a device?	X	
B. Is the device exempt from 510(k) by regulation or policy?		X
C. Is device subject to review by CDRH?	X	
D. (i) Are you aware that this device has been the subject of a previous NSE decision? (ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?		X

	Yes Present Omission Justified	No Inadequate Omitted
<p>E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer</p> <p>(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)</p>		X
<p>F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:</p> <p>* Device trade or proprietary name</p> <p>* Device common or usual name or classification name</p> <p>* Establishment registration number (only applies if establishment is registered)</p> <p>* Class into which the device is classified under (21 CFR Parts 862 to 892)</p> <p>* Classification Panel</p>	<p>X</p> <p>X</p> <p>X</p> <p>X</p> <p>X</p>	

JAN 7 1994

10
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		Yes Present Omission Justified	No Inadequate Omitted
*	Action taken to comply with Section 514 of the Act	X	
*	Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)	X	
*	A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	X	
*	For class III devices only, a class III certification and a class III summary	N/A	
*	Photographs of the device (Drawings of the Device in attached Operations Manual)		X
*	Engineering drawings for the device with dimensions and tolerances (Drawings of the Device in attached Operations Manual. Dimensions and tolerances not relevant to this submission (expansion of indications))	N/A	


JAN 7 1994

11

	Yes Present Omission Justified	No Inadequate Omitted
--	--------------------------------------	-----------------------------

* The marketed device(s) to which equivalence is claimed including labeling and description of the device	X	
* Statement of similarities and/or differences with marketed device(s)	X	
* Data to show consequences and effects of a modified device	X	
II. Additional Information that is necessary under 21 CFR 807.87(h):		
A. Submitter's name and address	X	
B. Contact person, telephone number and fax number	X	
C. Representative/Consultant if applicable	N/A	
D. Table of Contents with pagination	X	
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	X	

JAN 7 1994

12 

		Yes Present Omission Justified	No Inadequate Omitted
--	--	--------------------------------------	-----------------------------

III. Additional Information that may be necessary under 21 CFR 807.87(h):			
A. Comparison table of the new device to the marketed device(s)		X	
B. Action taken to comply with voluntary standards		N/A	
C. Performance data			
marketed device			
bench testing		N/A	
animal testing		N/A	
clinical data		N/A	
New device (Same as marketed device; new indication for use)			
bench testing		X	
animal testing		N/A	
clinical data		N/A	
D. Sterilization information		N/A	
E. Software information			
Same software as in currently marketed AS40A Infusion Pump.		N/A	

JAN 7 1994

14 

	Yes Present Omission Justified	No Inadequate Omitted
F. Hardware information Same hardware as in currently marketed AS40A Infusion Pump.	N/A	
G. Is this device subject to issues that have been addressed in specific guidance document(s)? Guidances on Infusion Pumps and on Software Controlled Devices do not apply to this submission since only change is new indication. (no changes to hardware or software) If yes, continue review with checklist from any appropriate guidance documents. If no, is 510(k) sufficiently complete to allow substantive review?	X	X
H. Other (specify)		

SEE LOGIC
FLOW CHART

Auto Syringe® AS40A Infusion Pump

Blood Infusion Indication

510(k) "Substantial Equivalence" Decision Making Process



Auto Syringe® AS40A Infusion Pump

Blood Infusion Indication

510(k) "Substantial Equivalence" Decision Making Process

Baxter Healthcare Corporation proposes to market the Auto Syringe® AS40A Infusion Pump for the infusion of whole blood and packed red blood cells. The Auto Syringe® AS40A Infusion Pump received premarket clearance under K903343 on July 17, 1990 and under K911289 on March 14, 1991, for continuous or intermittent infusion via intravenous, intra-arterial, epidural or subcutaneous routes of administration.

Using the logic flow chart entitled "510(k) "Substantial Equivalence" Decision-Making Process (Detailed)¹," we explain how we attained a "Substantial Equivalence" conclusion. A copy of the flow chart, with the decision path highlighted, appears at the end of this attachment.

New Device is Compared to Marketed Devices

Marketed devices: Auto Syringe® AS40A Infusion Pump, cleared under K903343 on July 17, 1990, and under K911289 on March 14, 1991.

Medfusion Model 2001 Syringe Infusion Pump, cleared under K905029 on December 24, 1990.

New device: We are adding a new indication to the currently marketed Auto Syringe® AS40A Infusion Pump, to infuse blood and blood components.

Does New Device Have Same Indication Statements?

No. The indications for use have been expanded to include the delivery of whole blood and packed red blood cells. The current indications are for the delivery of intravenous solutions, and drug solutions. The new indications will be the "delivery of intravenous solution, drug solutions, and whole blood

¹ FDA's Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program, June 30, 1986.

and packed red blood cells." The Operations Manual, which is attached to this submission, will be changed accordingly.

Do the Differences Alter the Intended Therapeutic /Diagnostic/etc. Effect (in Deciding, May Consider Impact on Safety and Effectiveness)?

No. The principal function of the Auto Syringe® AS40A Infusion Pump to deliver fluids at a controlled rate will remain unchanged.

To consider impact on safety, one would have to consider the safety of infusing whole blood and packed red blood cells via the Auto Syringe® AS40A Infusion Pump. The concern when infusing whole blood or packed red blood cells is to limit the rate of hemolysis. Studies using the Auto Syringe® AS-2FH and AS-5A Infusion Pumps, which have the same fluid delivery and pumping system as the AS40A, showed that the rate of hemolysis for these piston-type pumps is acceptable.

The effectiveness of the pump is not impacted by the broadening of its indications, since the current function of the pump has not been changed, and since it has been shown that the pumping mechanism properly delivers whole blood and packed red blood cells.

New Device has Same Intended Use and May be "Substantially Equivalent"

Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?

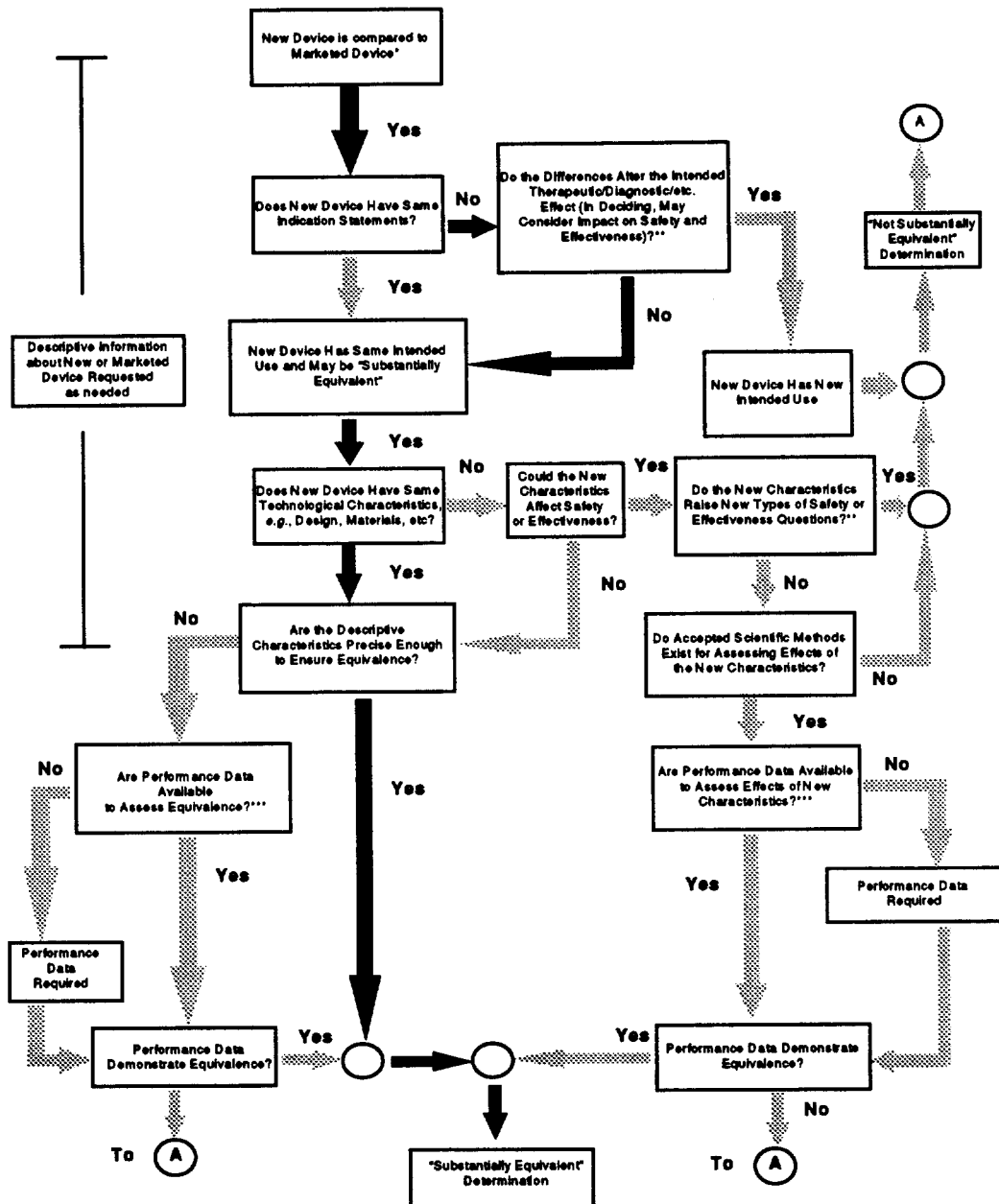
Yes. The AS40A Infusion Pump, with the added indication, remains the same as the currently marketed device. No changes in any technological characteristics, including design and materials, have been effected as a result of adding the new blood pumping indication.

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

Yes. In this 510(k) submission, which consists of a cover letter and several attachments, the product change (new intended use) is described, performance data for the new intended use are provided, manufacturing location is identified, and current and new labeling is provided.

Substantially Equivalent Determination

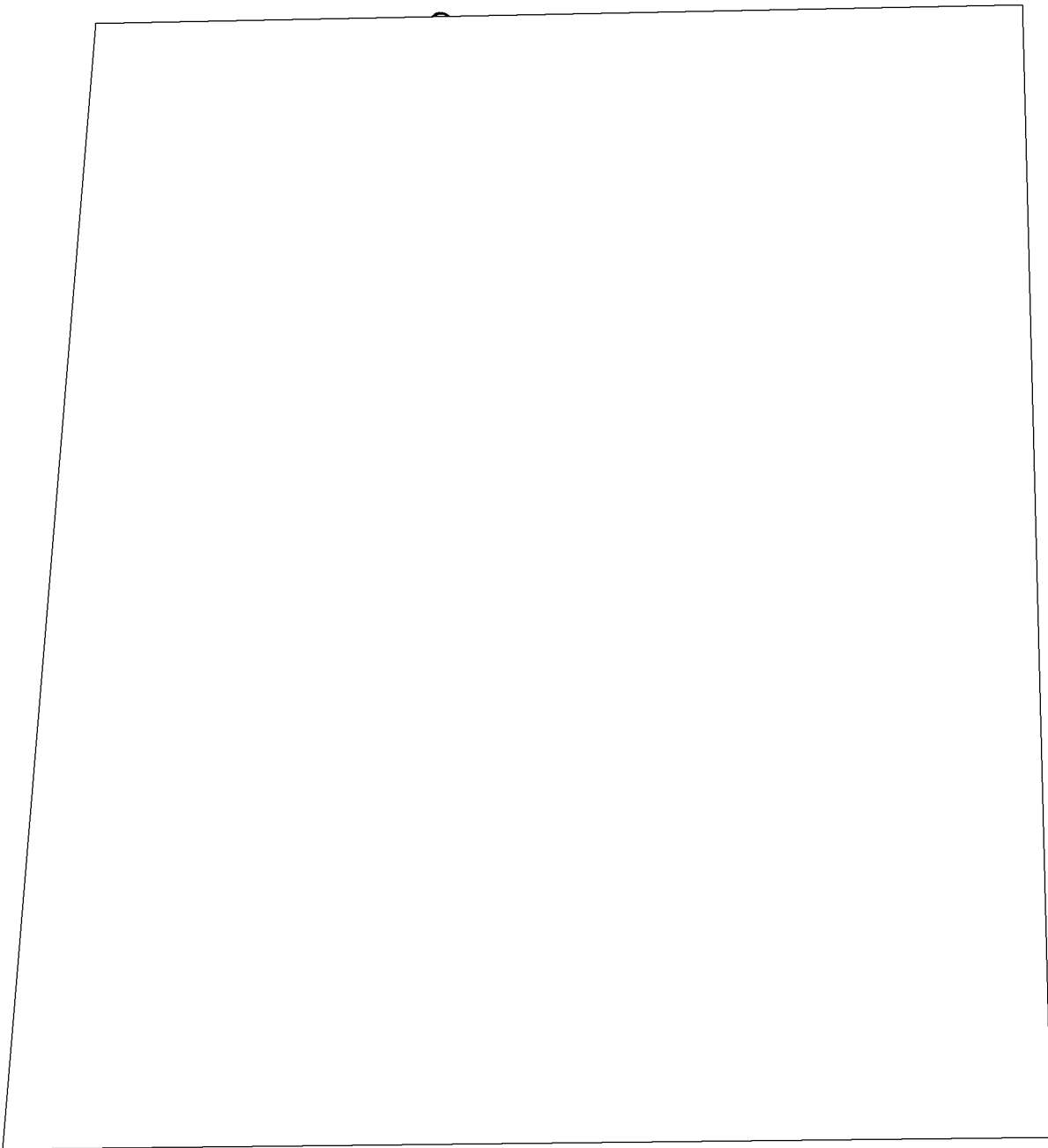
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



- * 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Pump Hemolysis Evaluation

510(k) Premarket Notification
Blood Infusion Indication for
Auto Syringe® AS40A Infusion Pump
January 7, 1994



TRAVENOL LABORATORIES, INC.

Morton Grove, Illinois 60053

R & D MEMORANDUM REPORT

8902

Accession no. _____

INFORMATION PRESENTED IN THIS REPORT IS NOT AUTHORIZED FOR USE OUTSIDE OF THE
COMPANY WITHOUT PRIOR APPROVAL OF THE DIRECTOR OF THE SUBMITTING DEPARTMENT

Copy to Scientific Services

Page 1 of 30

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JAN 7 1994

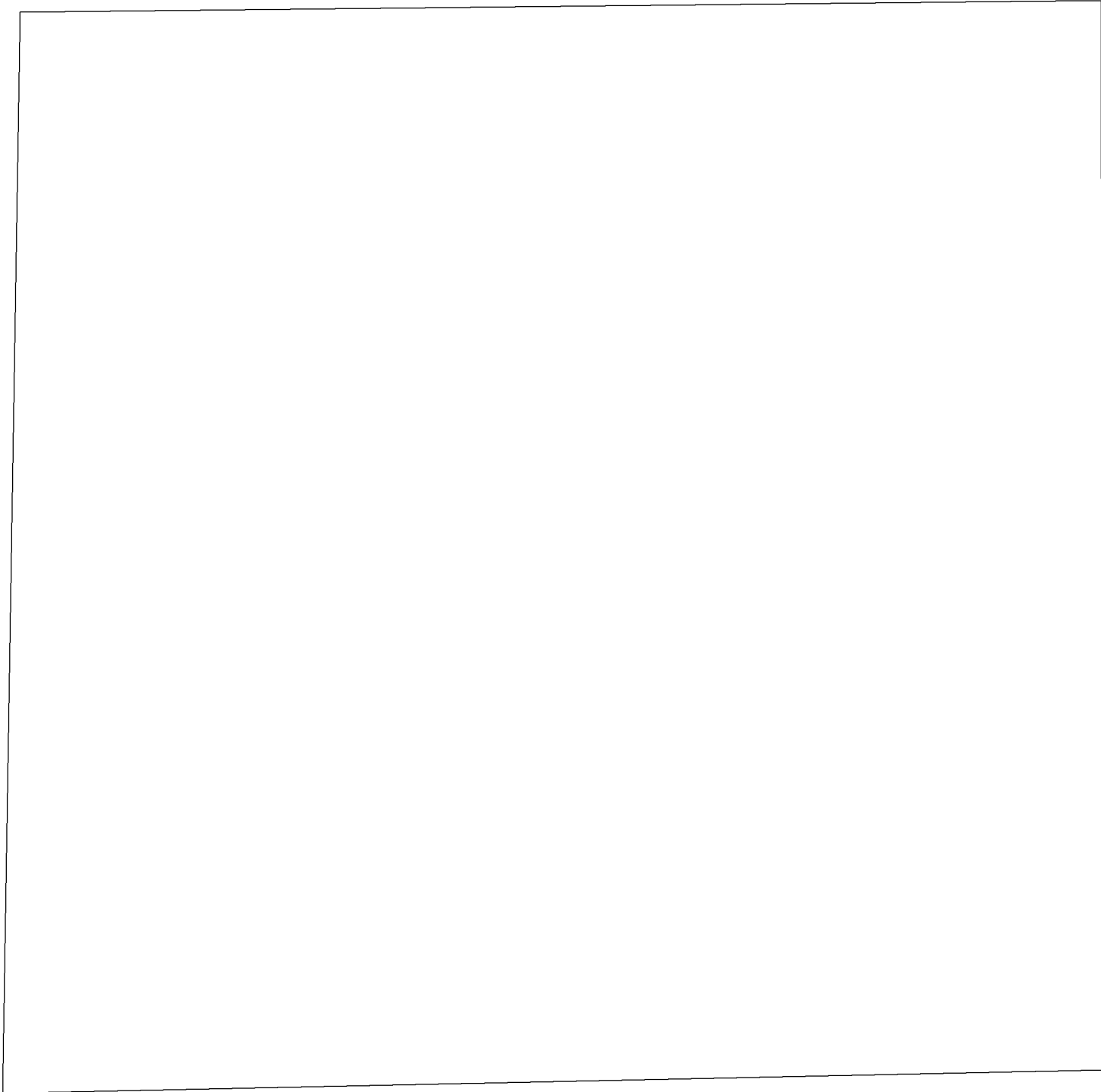
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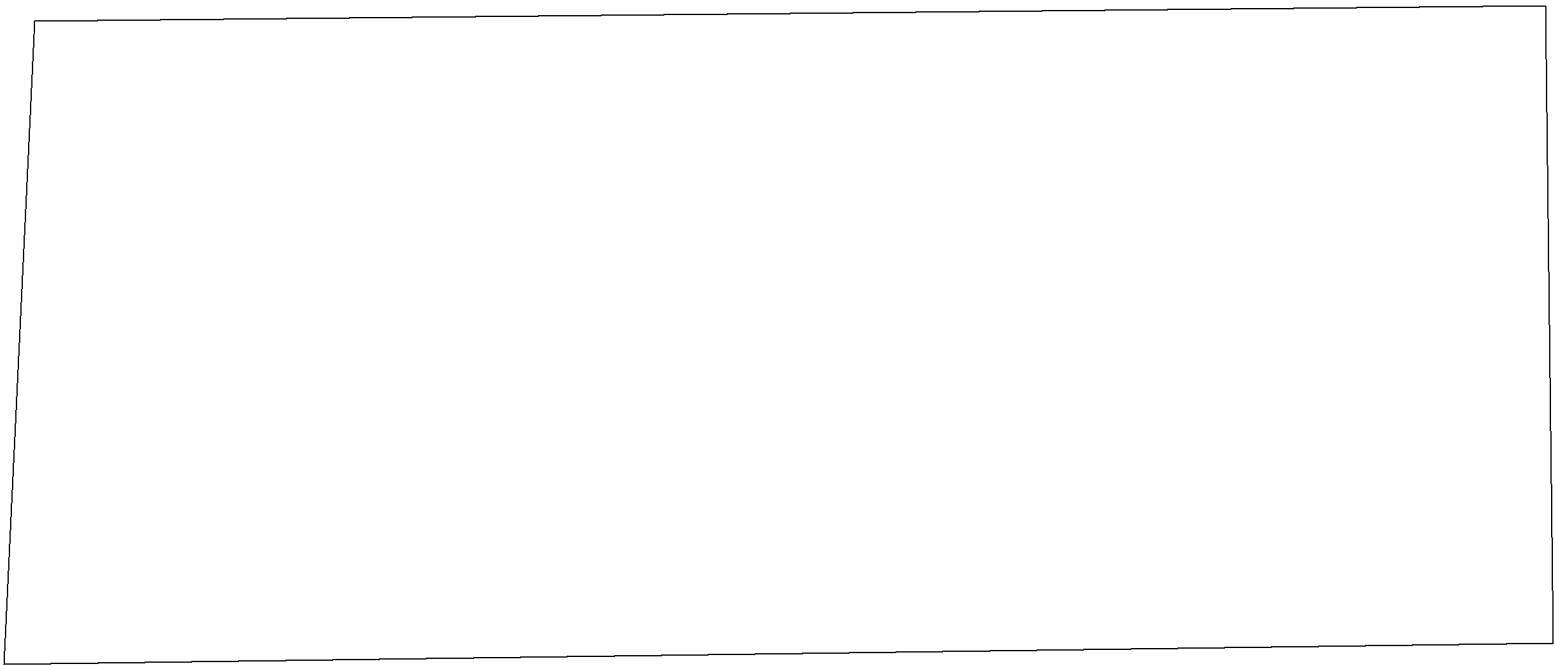
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JAN 7 1994

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JAN 7 1994

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JAN 7 1994

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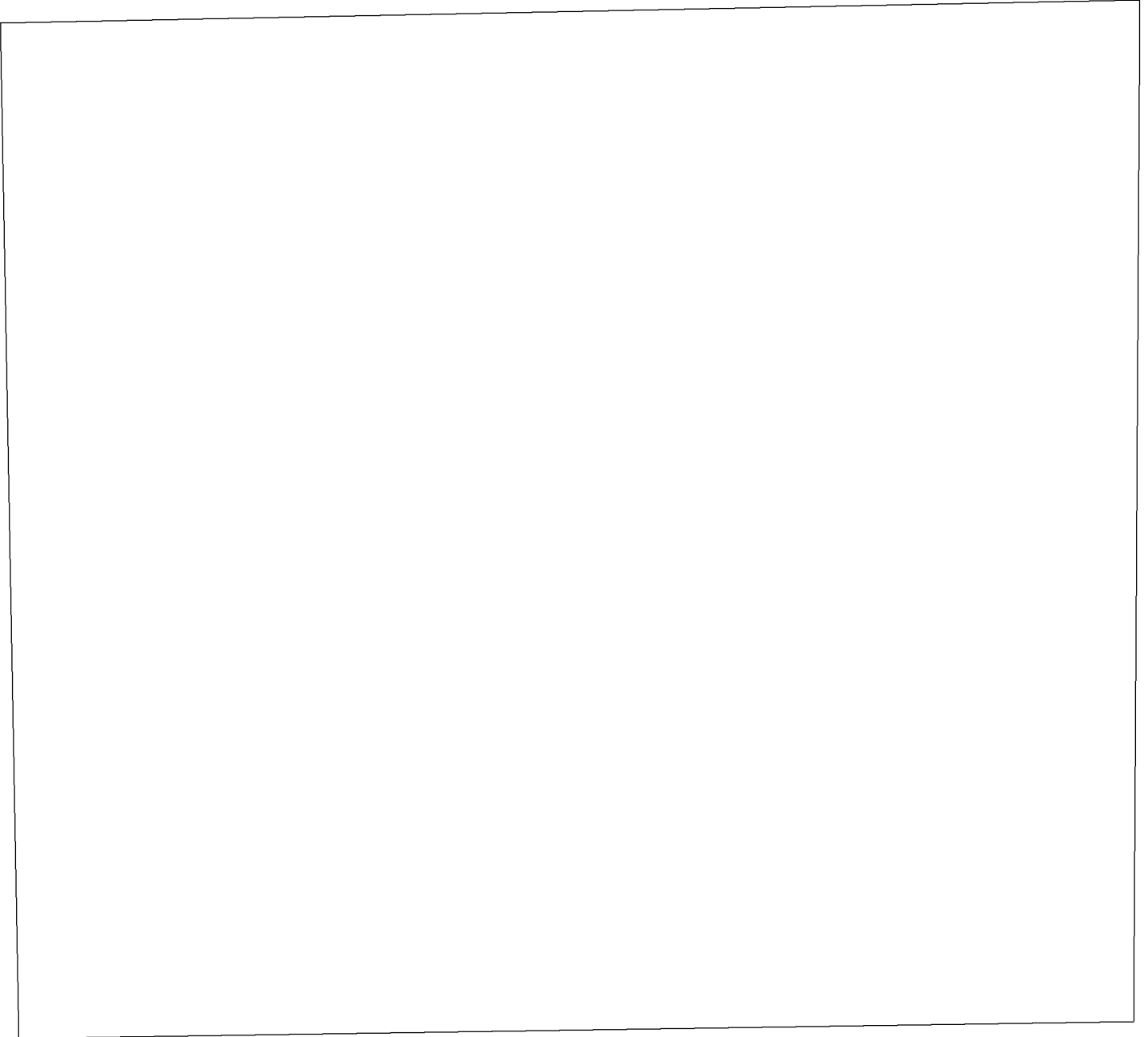
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JAN 7 1994

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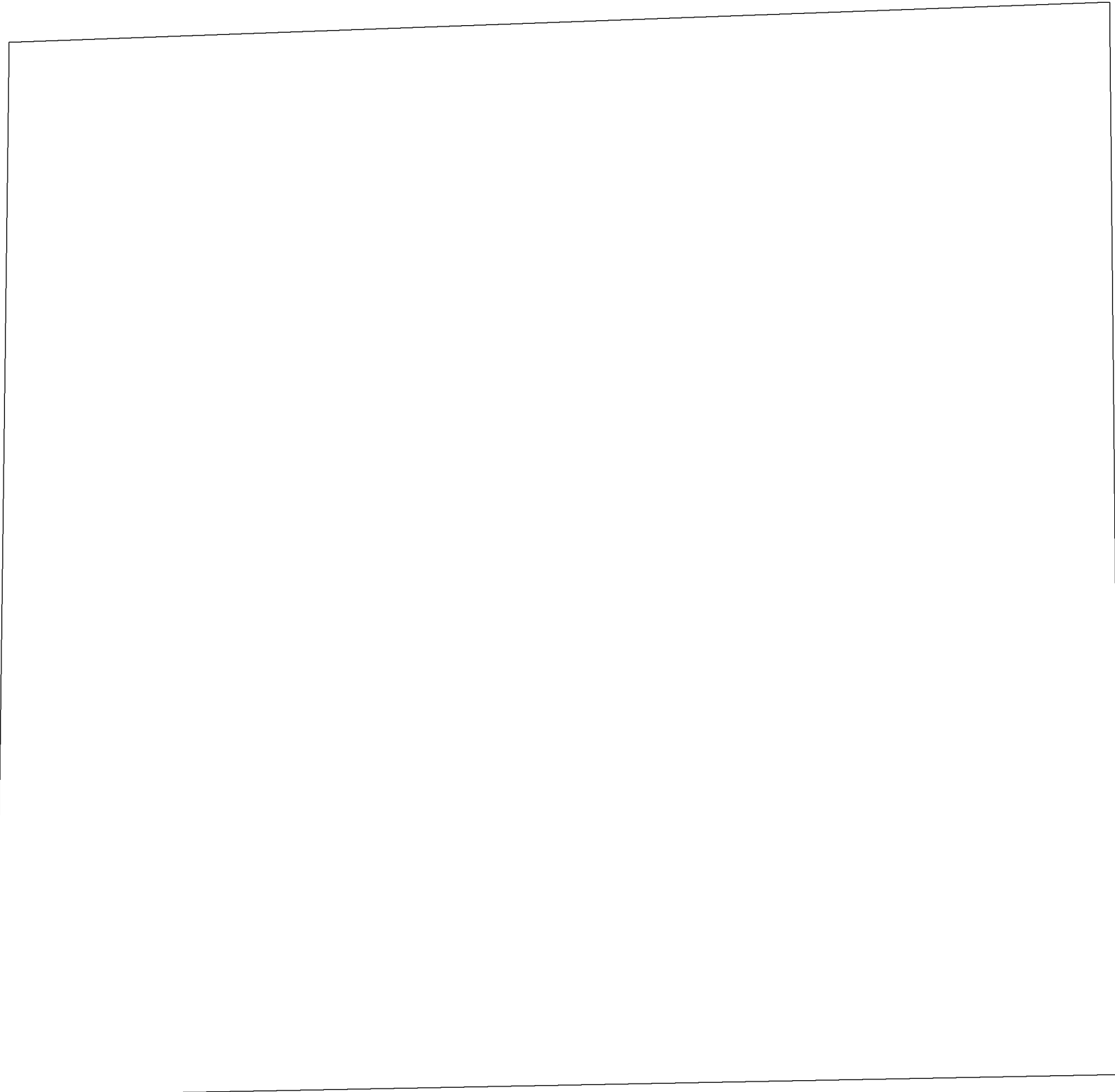
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JAN 7 1994

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JAN 7 1994 39

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JAN 7 1994

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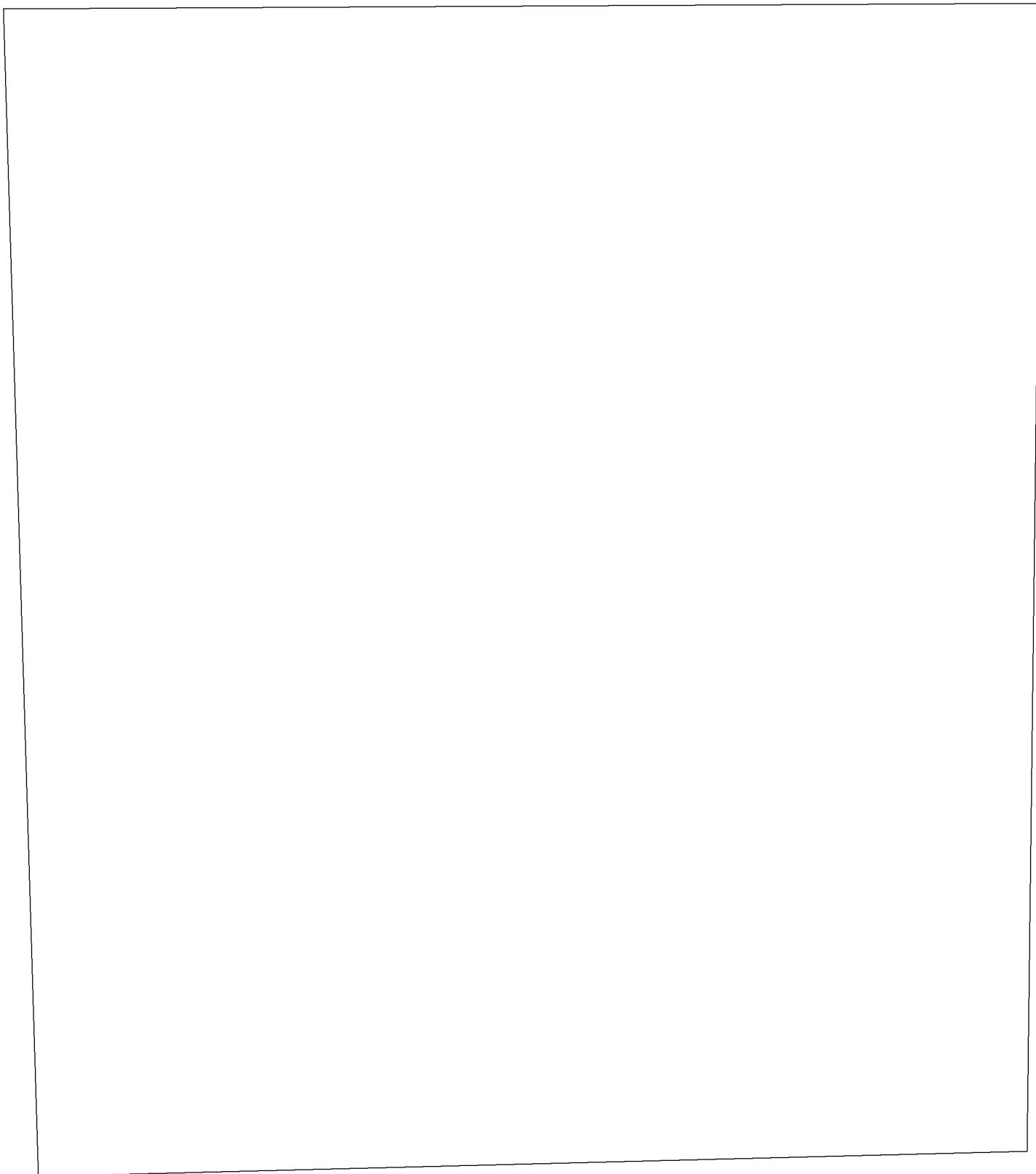
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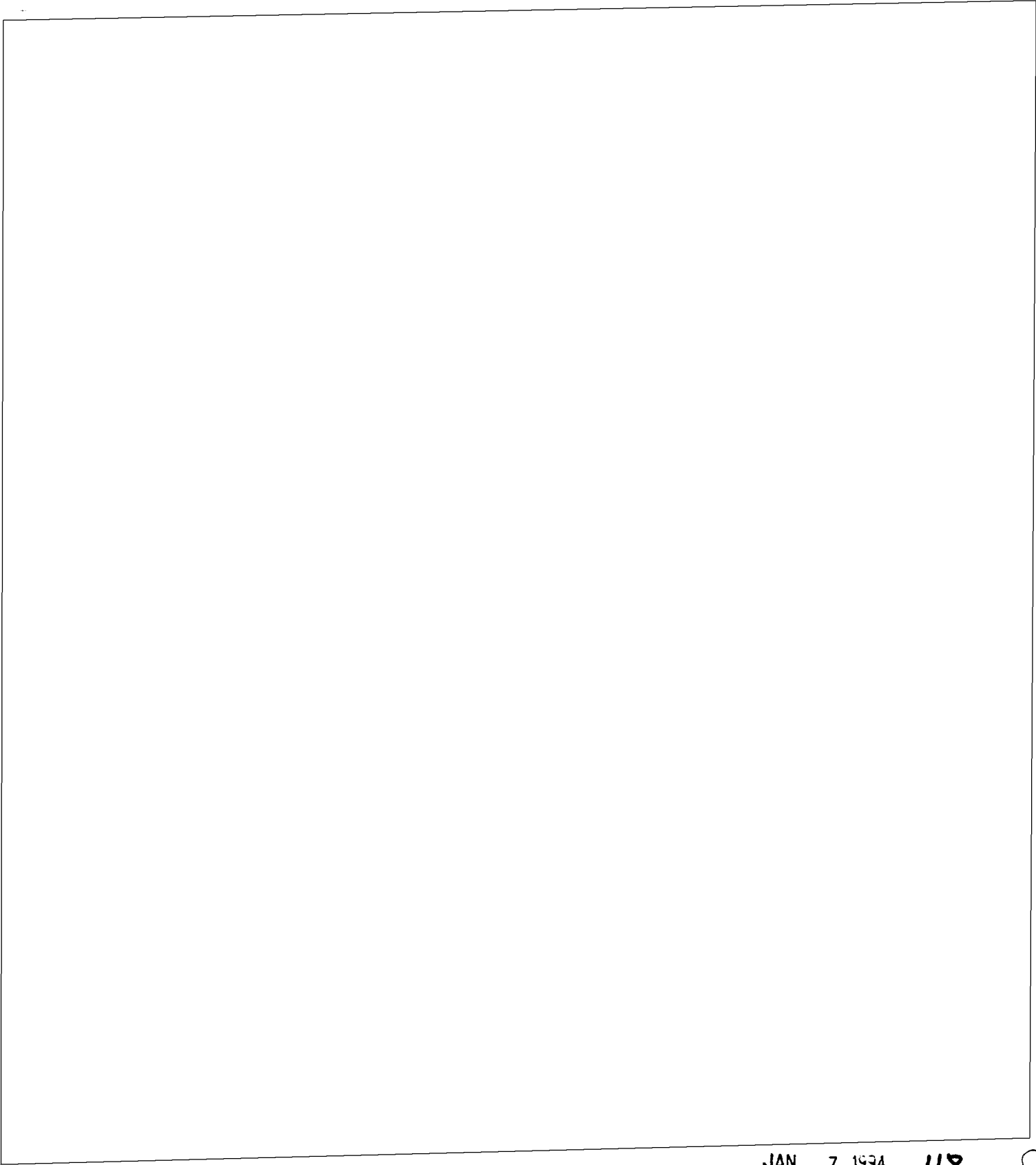


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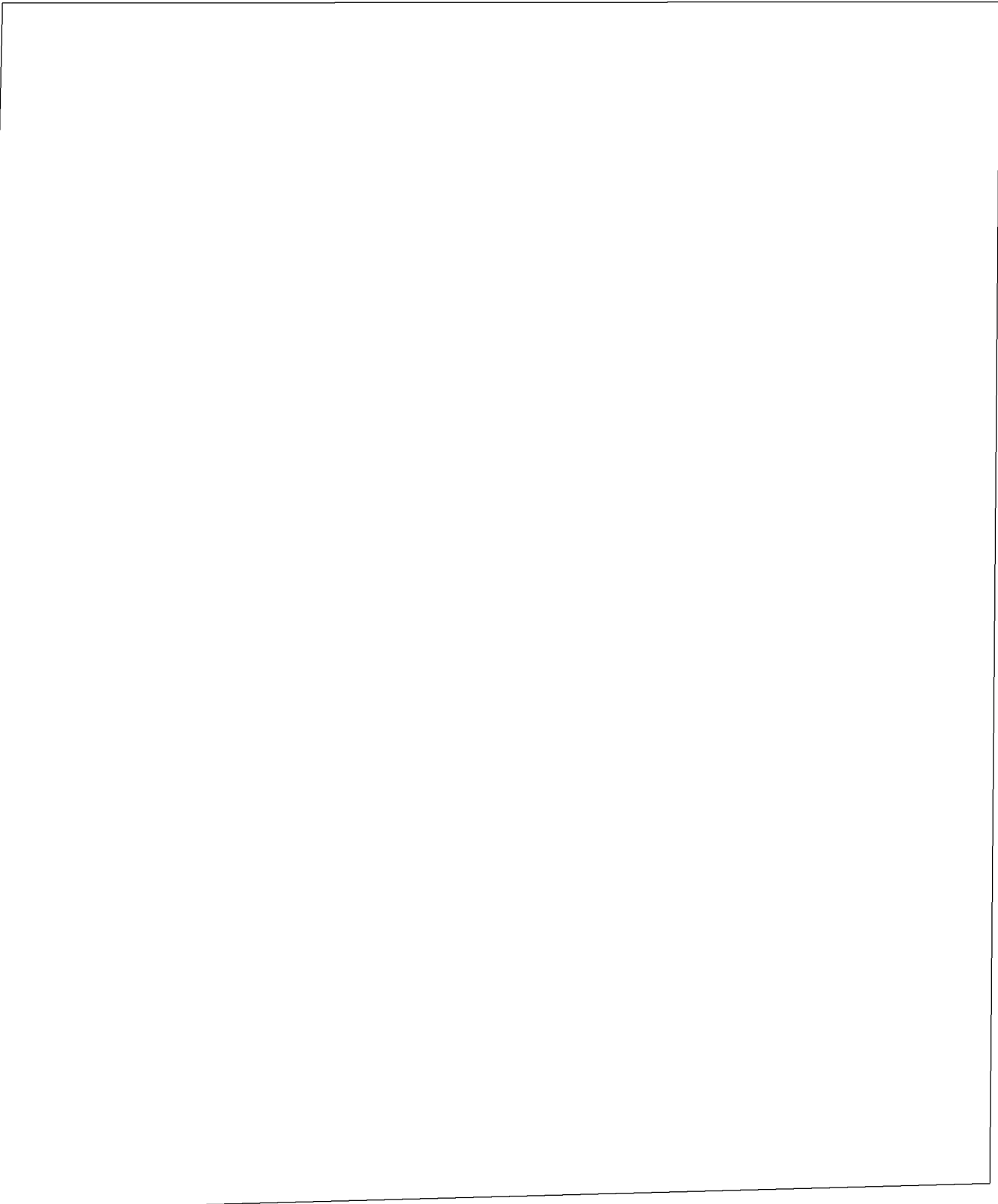
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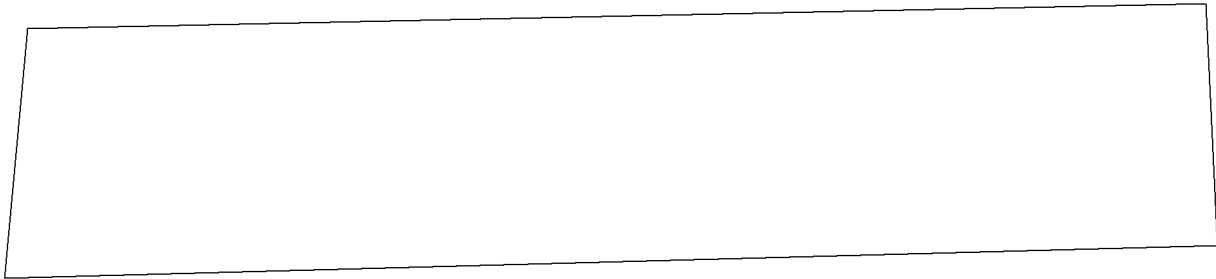
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COMPARISON BETWEEN
AS-5A, AS-2FH &
AS-40A

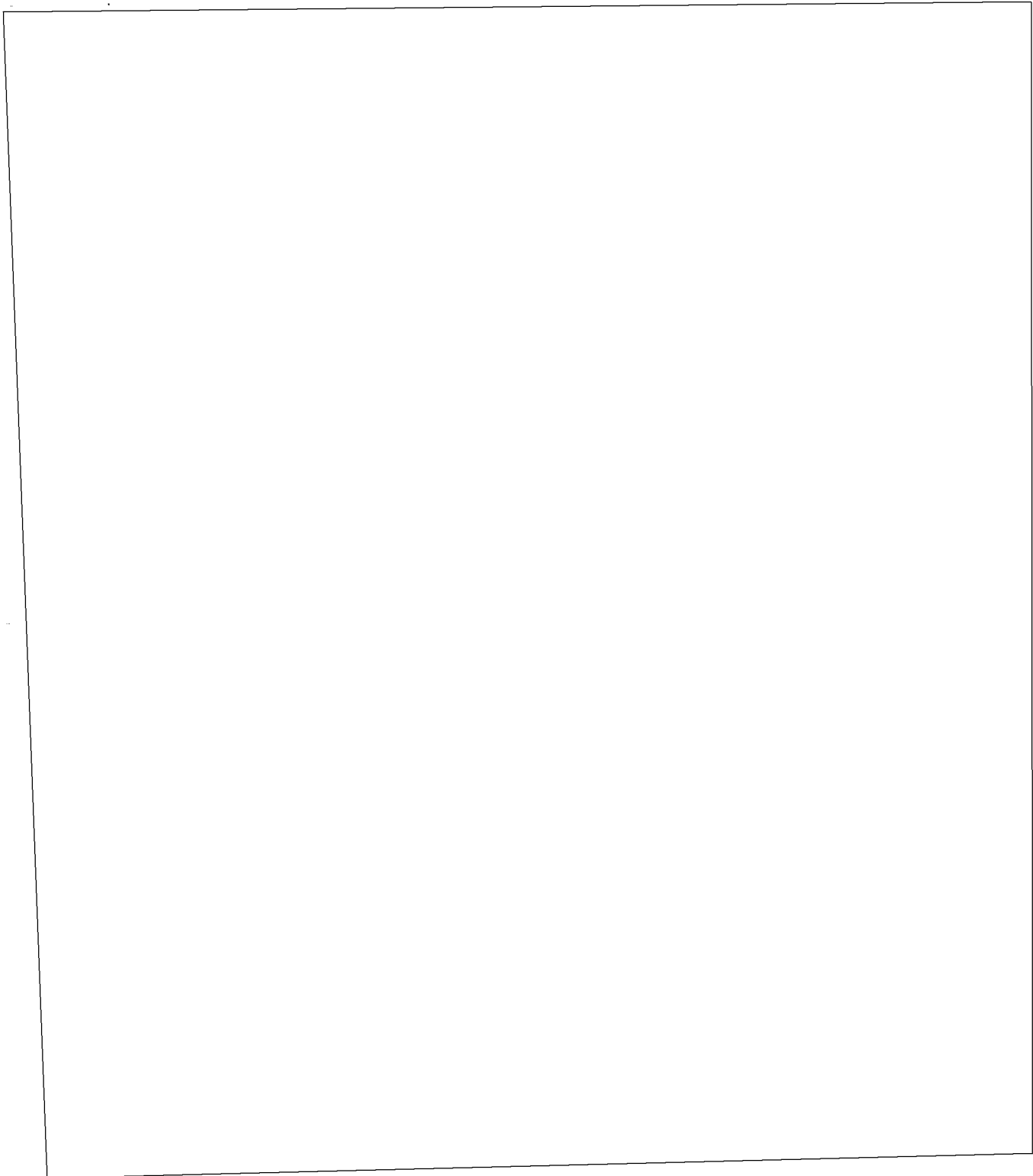
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510(k) Premarket Notification
Blood Infusion Indication for
Auto Syringe® AS40A Infusion Pump
January 7, 1994

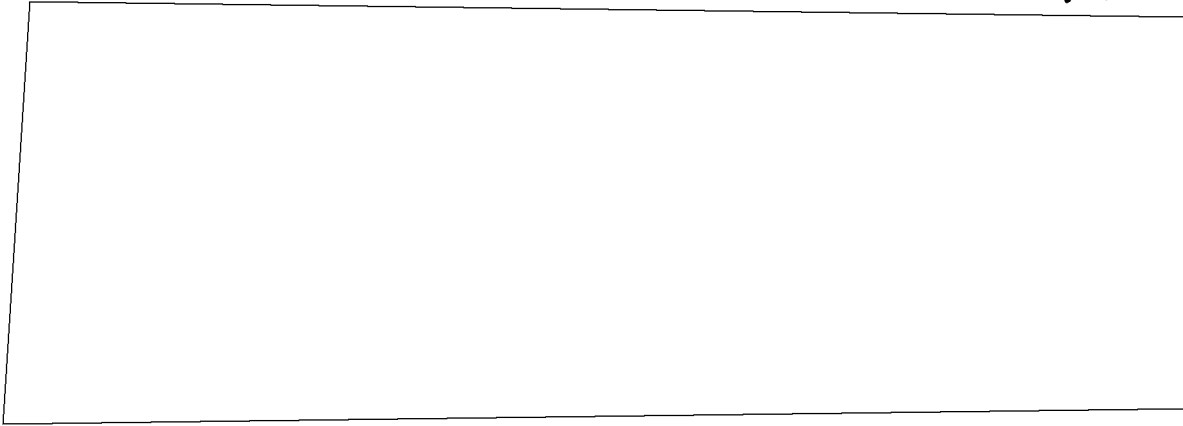


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510(k) Premarket Notification
Blood Infusion Indication for
Auto Syringe® AS40A Infusion Pump
January 7, 1994



510(k) Premarket Notification
Blood Infusion Indication for
Auto Syringe® AS40A Infusion Pump
January 7, 1994




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Ref.
Articles

510(k) Premarket Notification
Blood Infusion Indication for
Auto Syringe® AS40A Infusion Pump
January 7, 1994

Referenced Articles



Effects of intravenous delivery systems on infused red blood cells

JOHN S. GIBSON, RICHARD D. LEFF, AND ROBERT J. ROBERTS

Abstract: The effects of various intravenous delivery systems on the integrity of infused red blood cells (RBCs) were studied.

Using a factorial design, whole blood and packed RBCs were infused through i.v. delivery systems employing various combinations of i.v. tubing diameter and length, needle gauge, infusion rate (5 and 50 ml/hr), type of infusion pump (piston, diaphragm, or peristaltic operation), and type of blood product. The age and temperature of the blood products and the type of blood filter used were held constant. A 5-ml sample of the blood product obtained during each experimental run was analyzed for plasma free-hemoglobin to assess the degree of hemolysis. Osmotic fragility of the RBCs was evaluated by measuring the percentage of hemolysis in the blood products in various concentrations of sodium chloride solution.

Type of blood product and i.v. pump were the only variables significantly influencing RBC hemolysis. In both blood products, a greater degree of hemolysis occurred with the peristaltic-type pump than with the other types of pumps. In

packed RBCs, the diaphragm-type pump produced greater hemolysis than the piston-type pump, but hemolysis was similar in whole-blood samples. Regardless of the type of pump, more hemolysis occurred in whole blood at the 5-ml/hr infusion rate than at the 50-ml/hr rate, but the converse was true in packed RBCs. Samples of both blood products were less osmotically fragile than their respective controls at sodium chloride concentrations ranging from 0.30 to 0.50%.

Based on the results of this study, the piston-type pump in this study may be used for infusing either whole blood or packed RBCs; the diaphragm-type pump is suitable for administering whole blood. The optimal infusion rate appears to depend on the type of blood product.

Index terms: Blood; Concentration; Devices; Drug administration; Drug administration rate; Drug administration systems; Erythrocytes; Incompatibilities; Sodium chloride; Stability; Surgical supplies; Vehicles

Am J Hosp Pharm. 1984; 41:468-72

Several physical factors inherent to i.v. drug delivery systems have been shown to affect the rate and completeness of drug delivery.¹⁻⁴ Improved methods for i.v. drug administration have subsequently been developed, evaluated, and used to compensate for these recognized problems.^{2,3} However, these intravenous delivery systems ideally must satisfy multiple needs, including delivery of fluid and electrolyte therapy, drug therapy, and

various blood products. Intravenous delivery systems currently recommended for the administration of drugs have not been proven effective for the delivery of other injectable agents, including blood products. Definitive guidelines to prevent potential adverse effects that may be attributed to the infusion technique, such as red blood cell (RBC) hemolysis, have not been developed or examined. The intent of this investigation was to determine the influence

LT.COMDR. JOHN S. GIBSON, M.S., is Chief, Pharmacy Service, Naval Hospital, Beaufort, SC. RICHARD D. LEFF, PHARM.D., is Assistant Professor and Coordinator, Graduate Study Division of Clinical and Hospital Pharmacy, College of Pharmacy, University of Iowa, Iowa City. ROBERT J. ROBERTS, M.D., PH.D., is Professor, Divisions of Clinical Pharmacology and Neonatology, Departments of Pharmacology and Pediatrics, College of Medi-

cine, University of Iowa.

Address reprint requests to Dr. Leff at the College of Pharmacy, University of Iowa, Iowa City, IA 52242.

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of intravenous delivery systems and procedures on the integrity of administered whole blood and packed RBCs.

Methods

Selection of Study Variables. Six different physical variables potentially capable of affecting the degree of RBC hemolysis occurring during administration of the blood products were evaluated: i.v. tubing diameter, i.v. tubing length, needle gauge, i.v. flow rate, type of i.v. infusion pump, and type of blood product. These variables represent the principal ones that exist in i.v. delivery systems used in the clinical setting.

Intravenous administration tubing with three different intraluminal diameters were used. Standard i.v. extension tubing (Travenol Laboratories, Deerfield, IL 60015, product codes 2C0065 and 2C0066) had an internal diameter of 0.28 cm; intermediate-diameter i.v. extension tubing (Abbott Laboratories, North Chicago, IL 60064, product codes 6460 and 17087) had an internal diameter of 0.14 cm; and small-diameter i.v. extension tubing (Sea Medical Products, Glen Falls, NY 12801, product codes 02036 and 02060) had an internal diameter of 0.06 cm. All i.v. tubing was supplied in two different lengths. The short lengths for the standard-, intermediate-, and small-diameter i.v. tubing were 89, 91, and 91 cm, respectively; the long lengths were 140, 183, and 152 cm, respectively.

Two different needle gauges, an 18-gauge needle (Monoject 200, Sherwood Medical, St. Louis, MO 63103) and a 23-gauge needle (Abbott Laboratories, North Chicago, IL 60064, product code 4564), were selected for study. Two different i.v. flow rates, 5 and 50 ml/hr, were also selected. Preliminary testing showed that these rates allowed flow through the small-diameter extension tubing without triggering the occlusion alarm of the pump.

Three types of mechanical pumps designed for intravenous infusion were selected so that the basic mechanical method of pump operation could be evaluated rather than a specific manufacturer's product. A peristaltic-type pump (Flo-Gard 6000, Travenol), a diaphragm-type pump (Model 3-Life-care, Abbott), and a piston-type pump (Model AS-2FH, Auto-Syringe, Hooksett, NH 03104) were examined. The maximum allowable pressures (occlusion alarm pressures) for these mechanical devices are approximately 27, 15, and 11 lb/sq in, respectively.

Both whole blood and packed RBCs were obtained for the studies from the University of Iowa Hospital blood bank. The influence of age of the blood product,³⁻⁸ temperature of the blood product,^{9,10} and type of blood filter used^{8,11} will affect the integrity of the RBC. The age of the blood product was held constant by using whole blood or packed RBCs that were two to three days old. The stored blood prod-

ucts were refrigerated at 5 °C. Temperature was controlled by allowing blood products to equilibrate to room temperature for two hours before use, and the influence of the blood filter was held constant by using the same type of macroaggregate filter (Travenol, product code 2C2400).

Experimental Design. A factorial design involving a total of 144 experimental runs was used. Whole blood and packed RBCs were administered through each i.v. system that represented the specific combination of variables of the respective experimental run. During each experiment, blood products were mixed by gentle inversion of the bags every 15-30 minutes to ensure a uniform hematocrit. Before obtaining a sample for analysis, a volume of blood product equal to 1.5 times the i.v. tubing volume was infused and discarded. A 5-ml sample from each experimental i.v. system run was subsequently collected to determine the influence of the specific combination of variables under study. Each sample was immediately centrifuged (Model CS, International Equipment Co., Needham Heights, MA 02194) at a relative centrifugal force of 2260 g for 15 minutes, and the resulting supernatant was retained for free hemoglobin analysis. Control samples were obtained from each of the whole-blood or packed-RBC units after filtration but before being subject to infusion.

Laboratory Analysis. RBC Hemolysis. The degree of RBC hemolysis was quantified by measuring plasma free-hemoglobin in the supernatant. Any increase in plasma free-hemoglobin above control values (noninfused sample) was directly proportional to the number of RBCs lysed as a result of i.v. administration. The plasma free-hemoglobin content was quantified using a spectrophotometric technique¹² employing either a Co-Oximeter (Model IL182, Instrumentation Laboratory, Lexington, MA 02173) or a Gilford spectrophotometer (Model 240, Gilford Instrument Laboratories, Oberlin, OH 44074).

Osmotic Fragility. The degree of subhemolytic damage to the RBC was assessed on three whole-blood samples, three packed-RBC samples, and their respective controls using a modified version of Parpart's osmotic fragility test.¹³ These samples were selected to examine the full range of plasma free-hemoglobins obtained in the hemolysis studies.

Statistical Analysis. The experimental data were summarized by calculating the mean and the standard error of the mean (S.E.M.) plasma free-hemoglobin values for all variable combinations. Significant differences among the respective variable combinations were evaluated using analysis of variance.¹⁴ The predetermined level of significance was $\alpha = 0.05$.

Results

RBC Hemolysis. Data were collected for 138 of

56

the 144 possible experimental runs. In six cases no data could be obtained because the experimental conditions caused the infusion pressure to exceed the occlusion-alarm pressure of the pump.

Plasma free-hemoglobin concentrations for the samples ranged from 0 to 19,281 mg/dl. Because of this wide range of plasma free-hemoglobin values and the larger free-hemoglobin values within specific data sets, the total data obtained were categorized into two primary data groups for analysis: whole-blood data and packed-RBC data. These two data sets were further categorized by type of i.v. pump. The resulting mean \pm S.E.M. plasma free-hemoglobin values are displayed in Tables 1 and 2.

➤ Type of blood product and type of i.v. pump were the only variables significantly influencing RBC hemolysis. Only one other variable, i.v. flow rate, showed a trend toward affecting hemolysis ($p < 0.1$), while the remaining variables studied (i.v. tubing length, needle gauge, and i.v. tubing diameter) had no significant effect.

When analyzing the whole-blood data, a greater degree of hemolysis was detected with the peristaltic-type i.v. pump (144 ± 15 mg/dl) than with the diaphragm-type (8 ± 2 mg/dl) or piston-type (8 ± 5 mg/dl) i.v. pumps. Regardless of the type of pump, more hemolysis in whole blood occurred with the

5-ml/hr flow rate than with the 50-ml/hr flow rate, although hemolysis was significantly greater at 5 ml/hr only for the peristaltic-type pump.

Analysis of the packed-RBC data showed that greater hemolysis occurred with the use of the peristaltic-type i.v. pump (8237 ± 1000 mg/dl) than with the diaphragm-type (225 ± 37 mg/dl), and the diaphragm-type pump produced greater hemolysis than the piston-type (25 ± 4 mg/dl) i.v. pump. In contrast to the studies with whole blood, the samples of packed RBCs infused at 50 ml/hr exhibited more hemolysis than did the samples infused at 5 ml/hr, regardless of the type of pump. Hemolysis was significantly greater at 50 ml/hr for all three types of i.v. pumps.

Osmotic Fragility. Both the whole-blood and packed-RBC samples (Figure 1) were less osmotically fragile than their respective control samples at sodium concentrations ranging from 0.30 to 0.50%. There was no apparent difference between the infused samples and the noninfused control samples in either the sodium chloride concentration at which hemolysis began or the concentration at which 50% of the hemolysis was completed. Sodium chloride concentrations at which hemolysis began to occur ranged from 0.60 to 0.65% for whole-blood samples and from 0.50 to 0.55% for packed-RBC samples. Hemolysis was 50% complete at sodium chloride

Table 1.
Plasma Free-Hemoglobin Values* in Whole Blood and Packed Red Blood Cells (RBCs) Selected According to Blood Product, Type of I.V. Pump, and Flow Rate

Data Set	Blood Product		Type of I.V. Pump			Flow Rate	
	Whole	Packed RBC	Peristaltic	Diaphragm	Piston	5 ml/hr	50 ml/hr
All Data	53 \pm 9	2823 \pm 577	4015 \pm 766	107 \pm 24	16 \pm 3	891 \pm 232	1909 \pm 568
Whole-Blood Data			144 \pm 15	8 \pm 2	8 \pm 5	76 \pm 16	31 \pm 7
Peristaltic-type i.v. pump						203 \pm 17	86 \pm 10
Diaphragm-type i.v. pump						10 \pm 2	6 \pm 3
Piston-type i.v. pump						15 \pm 10	0 \pm 0
Packed-RBC Data			8237 \pm 1000	225 \pm 37	25 \pm 4	1706 \pm 424	4136 \pm 1127
Peristaltic-type i.v. pump						5007 \pm 477	12114 \pm 1320
Diaphragm-type i.v. pump						98 \pm 4	416 \pm 29
Piston-type i.v. pump						14 \pm 5	36 \pm 3

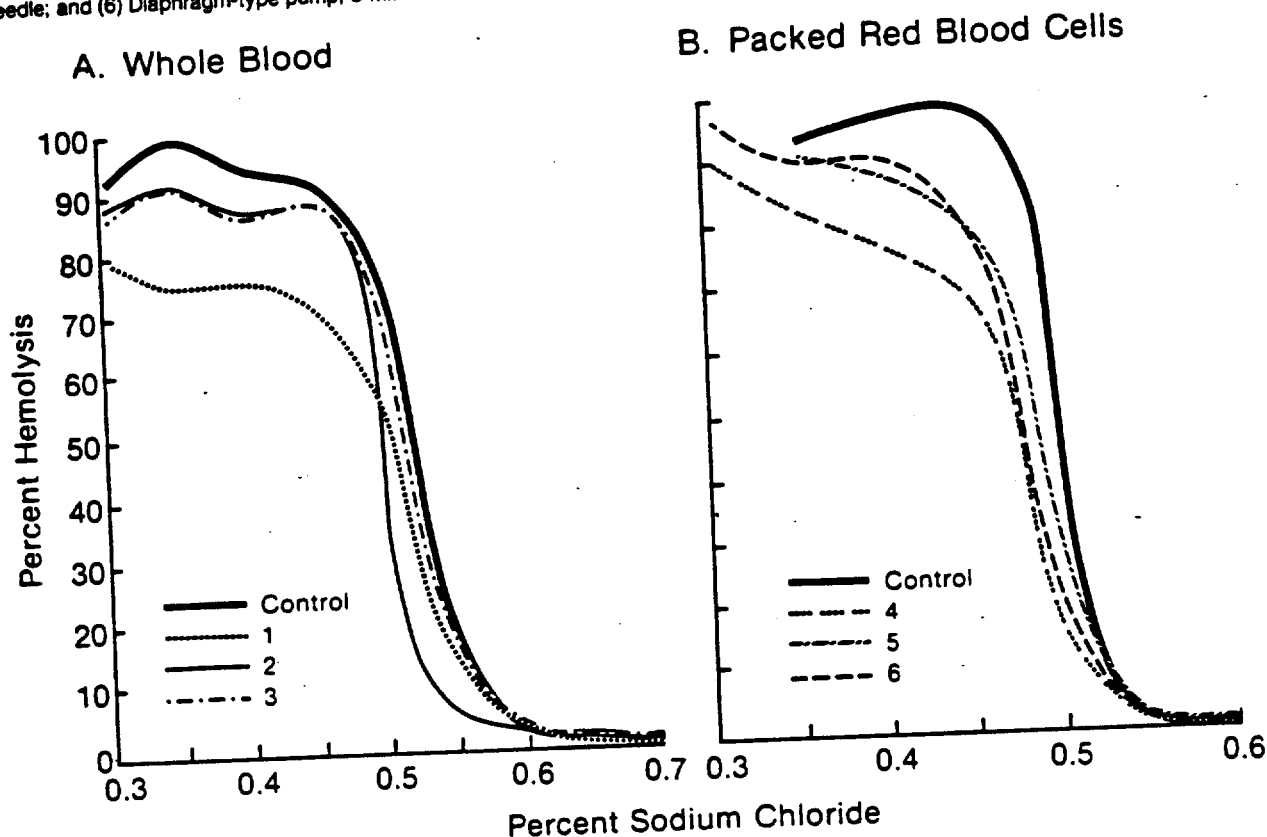
* Reported as mean \pm S.E.M. in mg/dl.

Table 2.
Plasma Free-Hemoglobin Values* in Whole Blood and Packed Red Blood Cells (RBCs) Selected According to Other Study Variables

Data Set	I.V. Tubing Length		Needle Gauge		Intraluminal Diameter of Tubing		
	Short	Long	18	23	Standard	Intermediate	Small
Whole-Blood Data							
Peristaltic-type i.v. pump	136 \pm 20	153 \pm 24	152 \pm 23	137 \pm 21	105 \pm 26	157 \pm 18	171 \pm 31
Diaphragm-type i.v. pump	7 \pm 20	9 \pm 3	7 \pm 3	9 \pm 3	5 \pm 2	11 \pm 4	8 \pm 4
Piston-type i.v. pump	0 \pm 0	15 \pm 10	15 \pm 10	0 \pm 0	12 \pm 12	0 \pm 0	11 \pm 11
Packed-RBC Data							
Peristaltic-type i.v. pump	8550 \pm 1476	7862 \pm 1383	8255 \pm 1707	8220 \pm 1135	9257 \pm 1697	9657 \pm 1592	4984 \pm 1540
Diaphragm-type i.v. pump	213 \pm 51	237 \pm 58	220 \pm 54	231 \pm 54	229 \pm 55	281 \pm 71	108 \pm 5
Piston-type i.v. pump	24 \pm 5	27 \pm 5	27 \pm 5	23 \pm 5	19 \pm 7	21 \pm 7	36 \pm 4

* Reported as mean \pm S.E.M. in mg/dl.

Figure 1. Osmotic fragility curves showing percentage hemolysis in varying concentrations of sodium chloride for selected samples of whole blood (left) and packed red blood cells (right) and their respective controls. Each of the curves represents an experimental run using the following combinations of study variables: (1) Piston-type pump, 5-ml/hr flow rate, small-diameter and long-length tubing, and 18-gauge needle; (2) Diaphragm-type pump, 50-ml/hr flow rate, small-diameter and long-length tubing, and 18-gauge needle; (3) Peristaltic-type pump, 5-ml/hr flow rate, small-diameter and long-length tubing, and 23-gauge needle; (4) Piston-type pump, 5-ml/hr flow rate, small-diameter and long-length tubing, and 18-gauge needle; (5) Peristaltic-type pump, 5-ml/hr flow rate, small-diameter and long-length tubing, and 23-gauge needle; and (6) Diaphragm-type pump, 5-ml/hr flow rate, small-diameter and short-length tubing, and 23-gauge needle.



concentrations ranging from 0.50 to 0.52% for whole-blood samples and from 0.47 to 0.50% for packed-RBC samples.

Discussion

The type of i.v. infusion pump used, the type of blood product administered, and the i.v. flow rate are important variables influencing the extent of RBC hemolysis in infused blood products. The piston-type i.v. pump is ostensibly the preferred mechanical device, as it produced the least degree of hemolysis of both whole blood and packed RBCs. It cannot be assumed that other infusion devices with similar modes of operation (piston, diaphragm, or peristaltic) will affect RBC hemolysis identically to the devices tested. Differences in the design and performance of i.v. infusion devices require that testing be performed to establish the effect of a particular device on RBC hemolysis.

Consistent with previous reports, the most extensive hemolysis resulted when packed RBCs were

administered.^{8,15} The peristaltic-type pump appeared to produce greater hemolysis of packed RBCs than the two other types of pumps. It was surprising to observe that greater hemolysis of packed RBCs occurred at the 50-ml/hr i.v. flow rate than at the 5-ml/hr flow rate and that more hemolysis of whole blood occurred at the 5-ml/hr rate. These results may explain the apparent conflicting reports of increases,^{5,6} decreases,^{7,8} and no alteration¹⁶ in plasma free-hemoglobin with increasing i.v. flow rates. Additional studies will be required to determine the mechanism for the apparent paradoxical relationship of flow rate and RBC hemolysis with packed RBCs versus whole blood. The viscosity of blood is one important factor that may explain this relationship. Hematocrit, shear rate, and red cell deformability are three major factors that influence viscosity.¹⁷ For example, as the hematocrit is increased from 50% to 80%, the viscosity of blood is tripled.

Increases,^{6,15} decreases,^{5,9} and no change¹⁶ in plasma free-hemoglobin have been reported to

occur as a result of an increasing needle bore. Increasing the length and intraluminal diameter of i.v. tubing has been shown to increase^{9,18} and decrease¹⁸ respectively, the extent of hemolysis. Our results suggest that small and variable changes in plasma free-hemoglobin can occur as a result of varying i.v. tubing length or intraluminal diameter and needle gauge. These changes were not significant under the conditions described and, thus, consideration of specific procedures or guidelines for their regulation does not appear justified. However, care must be taken when administering RBC products faster than 50 ml/hr, as the small-diameter tubing may limit the maximal rate of blood infusion. This effect was obvious from our inability to collect samples from six experimental runs because the pressure required for administration exceeded the limits of the occlusion alarm in the peristaltic-type (two samples) and diaphragm-type (four samples) i.v. pumps. The combination of factors that were common to the experiments in which data were unobtainable included the administration of packed RBCs through i.v. tubing having a small intraluminal diameter (0.06 cm) at a fast (50 ml/hr) i.v. flow rate.

Osmotic fragility of RBCs was also examined to evaluate whether the infusion process caused sub-hemolytic changes. An increase in osmotic fragility could theoretically reduce postinfusion RBC survival or function and thereby compromise the therapeutic effectiveness of the administered blood product. As shown in Figure 1, there was no increase in osmotic fragility secondary to the infusion process. In fact, the stability of the RBC to mechanical trauma appeared to be increased. This may have resulted from hemolysis of susceptible RBCs during infusion. The remaining RBCs would have been more resistant to subsequent osmotic trauma.

Conclusion

Unfortunately, there are no currently available guidelines for acceptable levels of hemolysis in blood products secondary to the infusion process. This imposes severe restrictions on the ability to develop definitive policies and procedures for RBC administration. One report suggests that 0.2% is a clinically acceptable level of hemolysis,⁷ but this recommendation is not based on objective evidence, and further studies may conclude that a greater level of hemolysis is allowable.

Based on the results obtained and the so-called acceptable level of hemolysis, the following recommendations are proposed. The diaphragm-type i.v. pump is suitable for administration of whole blood, and the piston-type i.v. pump is suitable for infusion of both whole blood and packed red blood cells. The needle gauge, intraluminal diameter of the i.v. tubing, and length of the i.v. tubing used are not

important factors as long as the anticipated flow rate is less than 50 ml/hr. Adjustment of existing infusion rates to minimize hemolysis must take into consideration the type of blood product (whole blood or packed RBCs) being given. Whether the significant differences in hemolysis resulting from infusion rates of 5 ml/hr versus 50 ml/hr are clinically important remains to be established.

The blood products employed in this experiment were uniformly two to three days old. The results of this study should not be extrapolated to the use of older blood products. Following the suggested administration recommendations above, it is unlikely that hemolysis in infused blood products would exceed 1%.

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of errors) were recorded. Of 223 recommendations to physicians (category 3), 215 were accepted and resulted in changes in therapy. As shown in Table 1, the majority (58.4%) of interventions were in category 3 (recommendations), while 38.2% were category 1 errors and 3.4% were category 2 errors.

This method of documenting pharmacists' clinical activities in a decentralized unit dose distribution system demonstrates the impact that pharmacists can have on patient care and implies a financial impact.

Although no direct cost savings could be determined from the intervention data, such interventions can decrease patient morbidity and mortality, prevent extended hospitalization, reduce the number of unnecessary determinations of serum drug

concentration, decrease the number of unnecessary medications, or promote the use of less expensive medications or routes of administration and result in cost savings for the hospital.

Conclusion. Documentation of pharmacists' interventions in drug therapy demonstrated that these pharmacists had an impact on patient care that could potentially reduce costs.

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Table 1.
Pharmacist-Initiated Changes in Drug Therapy

Type of Error Identified or Change Recommended	No. Interventions
Transcription Errors (Category 1)	
Improper renewal date	39
Incorrect interval or scheduling	30
Failure to transcribe an order	26
Failure to discontinue a drug as ordered	25
Incorrect dose transcribed	12
Drug transcribed for incorrect patient	7
Incorrect drug transcribed	3
Incorrect route of administration	3
Other	1
	146
Prescribing Errors (Category 2)	
Incorrect dose prescribed	8
Incorrect drug prescribed	3
Drug prescribed for incorrect patient	1
Incorrect dosing interval prescribed	1
Incorrect route of administration	0
Other	0
	13
Recommendations (Category 3)^a	
Increase, decrease, or hold dose ^b	73
Discontinue a drug ^c	36
Order serum drug concentration determination	17
Change from i.v. to oral administration	16
Change scheduling of medication	16
Change drugs within a pharmacologic class	12
Increase or decrease dosing interval ^d	13
Discontinue order for serum drug concentration determination	8
Initiate a drug	6
Change dosage form (e.g., tablet to liquid)	4
Change route of administration (other than i.v. to oral)	2
Change drug or dose because of pharmacist-identified drug interaction ^e	2
Other	18
	223

^a Unless otherwise indicated, recommendations were accepted.

^b Four recommendations were rejected by physician.

^c Two recommendations were rejected by physician.

^d One recommendation was rejected by physician.

^e One recommendation was rejected by physician.

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Influence of two piston-type infusion pumps on hemolysis of infused red blood cells

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Intravenous delivery systems have traditionally been designed to provide accurate delivery of fluid therapy. However, many other substances are administered through these same systems including red blood cell (RBC) products (whole blood and packed RBCs). Despite the frequency of RBC transfusions, there is little relevant information on the influence of various infusion factors or infusion devices on the integrity of RBC preparations.

Previous studies have examined in vitro the influence of the type of mechanical infusion device, length and diameter of i.v. tubing, gauge of needle, and rates of i.v. infusion on the integrity of RBC products. The type of pump device, type of blood product, and i.v. flow rate were found to affect the extent of hemolysis significantly.¹ The piston-type pump was the recommended device for adminis-

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tration of both whole blood and packed RBCs. However, it is not known whether all pumps with similar mechanisms of operation deliver whole blood or packed RBCs in an equivalent manner. The purpose of this study was to examine the influence of two piston-type pumps with different piston diameters on the extent of hemolysis of whole blood and packed RBCs.

Methods

The two piston-type pumps evaluated are commercially available and are currently in use in a variety of clinical settings (IMED 960 and IMED 965, IMED Corporation, San Diego, CA). The mechanical operation of the two pumps is similar. The primary differences between these pumps are the diameter of the piston mechanism and the stroke volume of the piston chamber. The piston diameters and stroke volumes for the 965 and 960 models are 0.570 inches and 1.5 mL and 0.890 inches and 3.5 mL, respectively. The 965 model is specifically designed for the infusion of large-volume injectable solutions at relatively slow infusion rates (not exceeding 99.9 mL/hr).

Both whole blood and packed RBCs preserved with citrate phosphate dextrose with adenine (CPDA-1) were obtained for the study from the University of Iowa Hospital blood bank. The age of the blood product,²⁻⁵ temperature of the blood product,^{6,7} and type of blood filter used⁵⁻⁸ are known to affect the integrity of RBCs. The age of the blood product was held constant by using whole blood or packed RBCs that were between two and three days old. Temperature was controlled by allowing the blood products to equilibrate to room temperature for two hours before use, and a single type of macroaggregate blood filter was used (#2C2400, Travenol Laboratories, Deerfield, IL).

Five infusion rates (5, 10, 25, 50, and 100 mL/hr) were used in the study. Since previous reports showed that needle gauge did not influence the extent of RBC hemolysis,^{1,9} only a 22-gauge needle (Monoject 200, Sherwood Medical, St. Louis, MO) was used.

Experimental Design. A 2 × 2 × 5 factorial design was used involving a total of 20 experimental runs. Whole blood and packed RBCs were infused through each i.v. system that represented the specific combination of factors of the respective experimental run. Blood products were mixed by gently inverting the bags every 15 minutes during the experiment to ensure a uniform hematocrit. Before obtaining a sample for analysis, a volume of blood product equal to two times the i.v. tubing and piston-chamber volume was infused under the conditions of the respective experimental run and discarded. For each of the experimental runs, duplicate 5-mL samples were collected in centrifuge tubes from the terminal end of the i.v. system. Each

sample was immediately centrifuged (Model CS, International Equipment Co., Needham Heights, MA) at a relative centrifugal force of 2260 g for 15 minutes, and the resulting supernatant was retained for plasma free-hemoglobin analysis. Preinfusion (control) samples were obtained from the end of the i.v. tubing that was disconnected just before entering the piston chamber of the pump. The preinfusion samples largely represented the influence of blood banking procedures and filtration on the plasma free-hemoglobin.

Laboratory Analysis. The degree of RBC hemolysis was quantified by measuring plasma free-hemoglobin before and after the infusion. Any increase in the plasma hemoglobin determination above the preinfusion sample values was directly proportional to the number of RBCs lysed as a result of being infused through the i.v. system under study. The plasma free-hemoglobin content was quantified using a spectrophotometric technique.¹⁰

Data Analysis. The plasma free-hemoglobin changes were determined by subtracting the hemoglobin values measured in the preinfusion samples from the values determined after the infusion process. The differences in the plasma free-hemoglobin values were summarized by calculating the mean values for the influence of the two piston-type pumps on the integrity of both whole blood and packed RBCs.

Results and Discussion

The mean changes in plasma free-hemoglobin values (mg/dL) by blood product and type of pump are shown in Table 1. The increase in plasma free-hemoglobin above the preinfusion values ranged from 0 to 92.9 mg/dL. The corresponding percentage of hemolysis ranged from 0 to 0.3%. Changes in plasma free-hemoglobin that resulted from the use of these piston-type pumps were generally very small and less than the free-hemoglobin values measured in the preinfusion samples.

Standards of the American Association of Blood Banks limit the maximum storage time of whole blood and packed RBCs to 35 days.¹¹ Typical plasma free-hemoglobin values measured in 35-day-old

Table 1.
Mean (± S.E.) Changes in Plasma Free-Hemoglobin Values (mg/dL) Resulting from Infusion of Whole Blood and Packed RBCs through Piston-Type Pumps*

Blood Product	IMED 960	IMED 965
Whole Blood	1.1 ± 0.2	0.3 ± 0.1
Packed RBCs	31.9 ± 12.5	1.2 ± 1.1

* Ten experimental runs were considered in the calculation of the mean values for each type of blood product.

stored whole blood and packed RBCs are 46 and 658 mg/dL, respectively.¹¹ The mean plasma free-hemoglobin values measured in whole blood and packed RBCs from our study samples after infusion were 3.5 mg/dL (range 2.2 to 4.4) and 69.0 mg/dL (range 12.0 to 117.6), respectively. Thus, the plasma free-hemoglobin values resulting from this study were less than the maximum allowable values for stored blood.

Conclusion

The infusion of whole blood and packed RBCs through the two piston-type pumps used in this study produced negligible hemolysis. Unfortunately, the degree of hemolysis that is clinically important has not been established.

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Calculator programs for weighted least-squares iterative fits in pharmacokinetics

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In recent years, nonlinear least-squares regression techniques for pharmacokinetic analysis have been implemented on programmable calculators. In a previous report,¹ we described two unweighted least-squares pharmacokinetic programs designed for an inexpensive and widely available handheld calculator. These two programs have been revised to allow for weighting of the experimental concentration data according to the commonly used weighting schemes.

Use of a weighted approach in pharmacokinetic least-squares fits has several advantages over the unweighted approach.² In the unweighted approach, estimation of the pharmacokinetic variables is performed by minimizing the sum of the squared absolute deviations between the measured and fitted points. The major problem with the unweighted fit is that the computer will essentially ignore terminal data (i.e., very low concentrations) if the data being fitted represent a wide range of concentrations. In the unweighted fit, the earlier time points (at which concentrations are higher) have substantially more effect in minimizing the sum of the squared absolute deviations than the terminal points (at which concentrations are lower). In the weighted least-squares procedures for curve fitting, the relative deviations (e.g., the percentage deviations) between the measured and fitted points are minimized rather than the absolute deviations. As a result, the overwhelming influence of the early time points is decreased and all data points contribute to a similar extent to the estimation of the pharmacokinetic variables.

The revised calculator programs, which are described in this paper, basically perform the same functions of the nonlinear least-squares computer programs that are commonly used in pharmacokinetics.

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(Best Available Copy)

Blood Flow, Needle Size and Hemolysis — Examining an Old Wives' Tale*

GERALD MOSS, PH.D., M.D., AND
CHARLES STAUNTON, B.S.

TO avoid hemolysis during blood sampling, the admonition has been, "Use a larger bore needle." Theoretically, experimentally and in our clinical experience, the reverse is true. To test this hypothesis, an experimental determination of the relation between needle size and hemolysis was performed.

METHODS

The blood to be examined was drawn from a dog whose stable, circulating red cells were "tagged" with ^{51}Cr (25,000 to 100,000 cpm per milliliter) as previously described.[†] Hemolysis was calculated from the appearance of the radioactive label in the serum or plasma.

The external jugular vein was catheterized under anesthesia with 5-cm (2-in) No. 8 Fr. polyvinyl tubing, capped with a puncturable stopper. A base-line sample was drawn slowly without a needle.

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†Supported in part by a grant from St. Peter's Hospital Research Fund.

†Moss G: Improved experimental red cell mass measurement. *Surgery* 66:771, 1969.

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Four samples were maximally aspirated into disposable plastic 5-ml syringes through each of 25, 22 and 20-gauge, 6-cm (2½-in) needles.

Three samples of heparinized blood were delivered into centrifuge tubes through each needle (No. 25, 22 and 20). Delivery pressure was maintained constant at 150 lb per square inch (10 × atmospheric), with the use of a power injector and steel syringe.

RESULTS

Maximal Syringe Aspiration

There was no detectable hemolysis with any needle size.

High-Pressure Delivery

Expression of blood through the 25-gauge needle led to 0.17 per cent hemolysis. This rose progressively to 8.3 and 15 per cent with larger needles (No. 22 and 20, respectively).

DISCUSSION

Hemolysis in a needle is related to flow velocity and conduit radius (R). Flow rate (Poiseuille's law) is proportional to R^4 . Area varies with R^2 . Velocity is proportional to R^2 (flow rate/area) (R^4/R^2). Turbulence (Reynold's number) is proportional to velocity × radius (that is, R^3). Velocity and turbulence increase with larger needles under constant delivery pressure.

In other words, smaller needles have reduced areas. However, flow rate is greatly decreased so that there is decreased velocity, turbulence and hemolysis.

Our clinical experience has been that most blood samples are smaller than 10 ml and can be drawn with a No. 25 needle. Our data and theoretical considerations support removal of the needle since forceful expression leads to hemolysis.

Thus, with maximal syringe aspiration, theoretical considerations indicate decreased hemolysis with smaller needles. Experimentally, no detectable hemolysis was produced by maximal aspiration of blood through No. 25, 22 or 20 needles. An increase in delivery pressure of 10 times (150 lb per square inch) produced minimal (0.17 per cent) hemolysis with the 25-gauge needle. This rose to lysis of 8.3 per cent and 15.0 per cent of the erythrocytes for 22 and 20-gauge needles, respectively.

The clinical application of these data is the use of fine-bore (such as 25-gauge) needles for blood sampling, without fear of hemolysis. The needle should be removed to empty the syringe.

We are indebted to Gwen Kohlenz, M.A. (Oxon) and Craig Daniels, A.A.S., for technical assistance.

103

Hemolysis in Blood Infused under Pressure

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During massive transfusions, blood frequently is infused under considerable pressure, often by means of a pneumatic device such as a Fenwal bag at pressures exceeding 300 mm Hg. Question naturally arises as to the danger of hemolysis, especially when needles of smaller caliber may be used during pediatric surgery. It might be assumed that hemolysis, under such circumstances, would increase with increasing age of the banked blood, increasing pressure used, and decreasing bore of the needles. Although the first two assumptions are correct, Moss and Stanton¹ found that due to greater turbulence in needles of larger bore, hemolysis actually increases when blood is forced through larger needles. Because their experiments were conducted under extreme conditions of pressure (150 psi) using freshly drawn heparinized blood, we wished to re-examine the problem under more normal clinical transfusion conditions.

METHOD

Blood was drawn from two healthy male donors with hematocrits of 41 and 43 per cent. It was stored in Fenwal plastic bags with citrate phosphate dextrose (CPD) anticoagulant, at 4 C. Tests were run at zero and seven days after collection with the blood equilibrated at room temperature. The blood was forced through needles of 18, 22, and 26 gauge at driving pressures of 100, 200 and 300 mm Hg delivered by means of a Fenwal bag system. To obtain a controlled pressure the system was modified by incorporation of compressed oxygen. Each test was carried out with triplicate aliquots of 10 ml. The samples were then spun down on an IEC)

TABLE 1. Hemolysis of Erythrocytes in Fresh Blood (Hct 43 Per Cent, Baseline Hgb 10.9 mg/100 ml)

Needle Bore (g)	Length (inches)	Driving Pressure (mm Hg)	Plasma Hemoglobin (mg/100 ml)
26	1/4	100	11.1
26	1/4	200	12.3
26	1/4	300	15.0
22	1/4	100	11.5
22	1/4	200	15.2
22	1/4	300	18.4
18	1/4	100	15.6
18	1/4	200	18.4
18	1/4	300	27.5

TABLE 2. Hemolysis of Erythrocytes in Blood Stored Seven Days (Hct 41 Per Cent, Baseline Hgb 22.3 mg/100 ml)

Needle Bore (g)	Length (inches)	Driving Pressure (mm Hg)	Plasma Hemoglobin (mg/100 ml)
26	1/4	100	23.0
26	1/4	200	27.0
26	1/4	300	32.1
22	1/4	100	29.1
22	1/4	200	34.3
22	1/4	300	38.7
18	1/4	100	31.6
18	1/4	200	37.8
18	1/4	300	44.5

centrifuge at $9,000 \times g$ for 10 minutes. Plasma was then extracted in Pasteur pipettes for hemolysis determinations using the Hanks benzidine method.² Readings were made on a Gilford spectrophotometer.

RESULTS

Hemolysis of erythrocytes was found to increase directly with driving pressure and with age of stored blood and, as shown by Moss and Stanton, with increasing needle bore (tables 1 and 2). The most severe of our conditions, 7-day-old blood driven through an 18-gauge needle under 300 mm Hg pressure, produced only 44.5 mg/100 ml of plasma

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hemoglobin, or an increase of 23.2 mg/100 ml over the seven-day plasma hemoglobin baseline of 22.3 mg/100 ml. Since hemolysis of less than 75 mg/100 ml is not considered to be of clinical significance in causing morbidity or mortality, none of the samples in our tests showed a significant degree of hemolysis.

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Persistent Atrial Arrhythmias Associated with Placement of a Swan-Ganz Catheter

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DEMETRIOS G. LAPPAS, M.D.‡

Since the introduction of the Swan-Ganz flow-directed balloon-tipped catheter,¹ bedside monitoring of pulmonary-artery (PA) and pulmonary-capillary-wedge (PCW) pressures has been employed with increasing frequency and safety. Accurate assessment of left-heart filling pressures in patients with myocardial infarction² and valvular heart disease with decompensation and fluid replacement in a variety of noncardiac conditions, such as extensive trauma and septicemia, can be carried out. The pulmonary capillary wedge pressure measurement can also be of particular value during the induction of anesthesia and intraoperative management of these patients, as well as those who are less seriously ill, but undergoing extensive surgery with major blood losses or fluid shifts.

Complications have included knotting of the catheter⁴ and perforation of the pulmonary artery.⁴ Arrhythmias have been encountered,

but those reported have been only premature ventricular contractions (PVC's) and, occasionally, runs of multiple PVC's, but not sustained ventricular tachycardia⁴ or ventricular fibrillation.⁵ The following are case reports of arrhythmias in two patients, atrial fibrillation and atrial flutter with varying block, the only atrial arrhythmias which have been encountered in the placement of 180 Swan-Ganz catheters.

REPORT OF TWO CASES

Patient 1. A 60-year-old man with degenerative arthritis of the right hip was scheduled for total hip replacement under general anesthesia with induced hypotension. Preoperative evaluation disclosed no abnormality and the ECC showed sinus rhythm. Anesthetic premedication was meperidine, 50 mg, promethazine, 25 mg, and scopolamine, 0.3 mg.

Arterial and central venous cannulae were inserted, and while these pressures and the electrocardiogram were continuously monitored, a Swan-Ganz catheter was passed into the right internal jugular vein. Atrial fibrillation occurred when the catheter entered the right atrium (Fig. 1A). The ventricular rate was 110/min and blood pressure was 150/80 torr. Anesthesia was then induced, but because the atrial fibrillation continued, the catheter was withdrawn. Forty minutes later, normal sinus rhythm spontaneously returned (Fig. 1B). Controlled hypotension was induced with pentolinium, and the operative and postoperative courses were uneventful.

Patient 2. A 42-year-old woman with moderately

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Does Transfusion Using a Syringe Infusion Pump and Small-Gauge Needle Cause Hemolysis?

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Hemolysis of two- and nine-day-stored sedimented red blood cells (hematocrit 65%), infused by a constant-rate syringe delivery pump through a 25-gauge needle was investigated. Fifteen-ml aliquots of blood were pumped through the system at flow rates of 10.6, 20.5, and 70 ml/hour. Plasma-free hemoglobin and potassium were measured and compared to controls. Significant red blood cell hemolysis occurred during passage through this infusion system, and the amount of hemolysis was greater with nine-day-stored cells. These cells showed more hemolysis with slower flow rates, but the two-day-stored cells were not affected by rate of flow.

LOW-BIRTH-WEIGHT infants in a neonatal intensive care unit often undergo multiple phlebotomies for a variety of clinical tests. Small-volume blood transfusions are required to replace this iatrogenic blood loss. In many clinical centers these transfusions are administered using a constant-rate syringe delivery infusion pump and a 25-gauge thin-wall scalp vein needle. The infusion pump applies pressure to a plastic syringe which contains the blood, gradually expelling it through the infusion set and needle. This apparatus permits relatively precise selection of the rate and volume of transfusion to patients for whom hemodynamic regulation is critical. Despite the widespread use of this technique of blood infusion, the possible hazards have not, to our knowledge, been investigated. We have assessed the resulting red blood cell hemolysis and the effects on the amount of hemolysis of rate of infusion and storage age of the blood transfused.

Materials and Methods

Seventeen units of blood were collected into quadruple packs by the standard technique using citrate-phosphate-dextrose (CPD) anticoagulant preservative solution. Storage temperature was 1 to 6 C. The red blood cells were allowed to sediment for 24 hours, resulting in a range of hematocrits of 55 to 75 per cent. Three 20-ml aliquots of two-day-stored sedimented cells were withdrawn into a 20-ml sterile plastic syringe. At room temperature (22 C) the red blood cells were pumped through a platelet infusion set with an in-line 170- μ filter and a 25-gauge thin-wall needle into siliconized test tubes at flow rates of 70.0, 20.5, and 10.6 ml/hour. A Razel infusion pump was used to provide continuous flow at the desired rates. Plasma was separated immediately. Free hemoglobin levels were determined using the chlorpromazine procedure of Collier,¹ and potassium was determined using the I.L. 343 Flame Photometer. The plasma remaining in the single pack was analyzed as a control. These procedures were repeated after nine days' storage on the same unit using a second pack from the original quadruple pack also as sedimented red blood cells.

Results

Our results indicate that significant red blood cell hemolysis may occur during transfusion using this infusion system (Table 1). The amount of hemolysis was greater with the red blood cells stored nine days, which demonstrated significantly higher values of both plasma hemoglobin and potassium compared to control values. There was wide variability between individual units of blood in susceptibility of red blood cells to hemolysis, as can be seen from the range of values obtained for plasma hemoglobin and, to a lesser extent, for plasma potassium. With the nine-day-stored red blood cells, somewhat greater hemolysis occurred at slower infusion speeds, a result we did not anticipate.

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JAN 7 1994

Volume 21
Number 6

66

Table 1. Plasma-Free Hemoglobin and Potassium of Blood Stored at 4 C and then Pumped through a 25-Gauge Needle

Flow ml/hour	Plasma-Free Hgb (mg/dl) Mean \pm 1 SD		Plasma K (mEq/l) Mean \pm 1 SD	
	2 days	9 days	2 days	9 days
Control	7.6 \pm 3.4	13.3 \pm 11.3	9.6 \pm 4.8	17.5 \pm 9.0
70	12.3 \pm 4.5	35.0 \pm 23.6	11.2 \pm 4.3	28.1 \pm 11.6
p value	p < 0.005	p < 0.005	NS	p < 0.025
20.5	12.4 \pm 6.5	44.1 \pm 38.4	11.7 \pm 5.4	27.2 \pm 9.0
p value	p < 0.025	p < 0.01	NS	p < 0.005
10.6	12.0 \pm 5.7	57.8 \pm 57.7	11.6 \pm 5.8	29.3 \pm 10.0
p value	p < 0.025	p < 0.01	NS	p < 0.005
No. of spec.	17	15	17	15

Discussion

Infusion of blood through narrow-gauge needles under pressure has been reported to result in hemolysis.² Many medical centers are now using constant-rate infusion pumps to give accurate delivery of transfused blood to newborns and other patients who may have a precarious hemodynamic status. For low-birth-weight infants it is also common practice to infuse blood through small-caliber needles into scalp veins. Mechanical hemolysis of transfused red blood cells is particularly hazardous to such patients. They are susceptible to the adverse effects of hyperbilirubinemia, which may be exaggerated by their immature hepatic enzyme systems. In addition, their small blood volumes render them sensitive to the cardiotoxic effect of the hyperkalemia that results from hemolysis. For such recipients there are no good figures available to indicate acceptable and unacceptable levels of hemoglobin escape.

The data indicate that nine-day-stored red blood cells, when transfused using this infusion system, suffer traumatic hemolysis. Calculated from the data, as much as 0.2 per cent of nine-day-stored red blood cells may be hemolyzed during infusion, an amount of hemolysis which seems tolerable under most circumstances. The two-day-stored red blood

cells were less susceptible to hemolysis by the infusion system.

Slow infusion rates are usually prescribed because of these recipients' unstable hemodynamic status. The data also suggest that hemolysis of red blood cells stored nine days may actually be increased at slower infusion speeds. For two-day-stored red blood cells, varying the infusion rate does not change the amount of mechanical hemolysis.

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107
67

CURRENT
LABELING

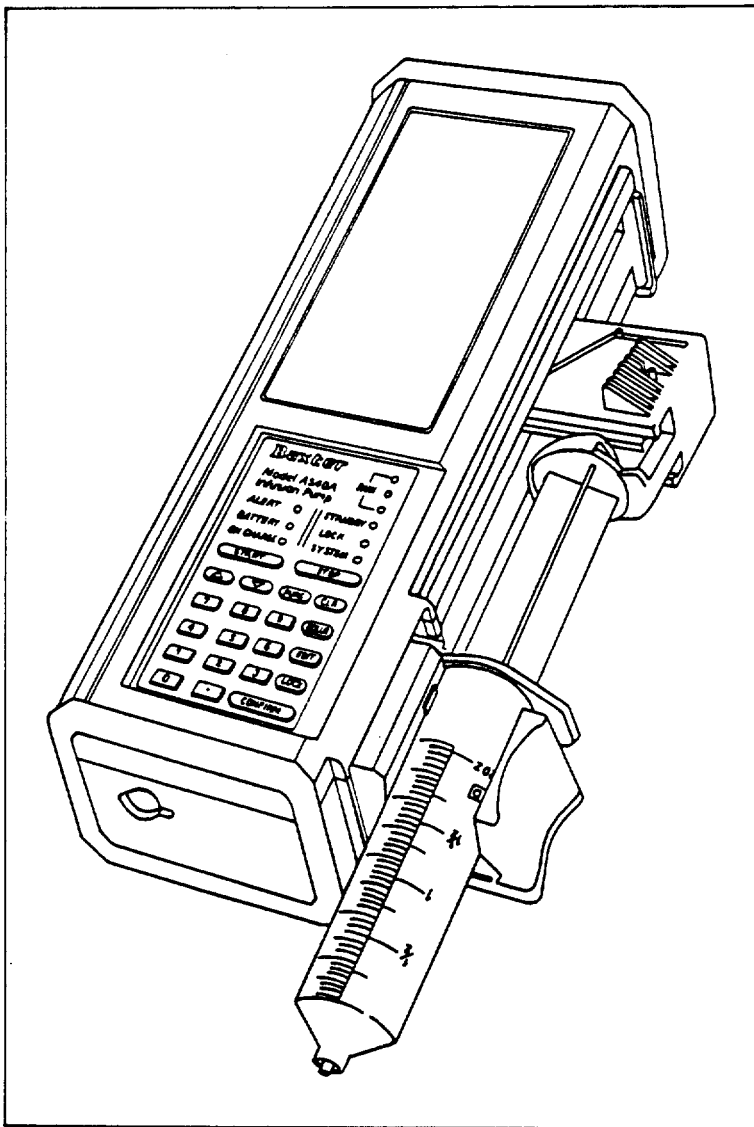
510(k) Premarket Notification
Blood Infusion Indication for
Auto Syringe® AS40A Infusion Pump
January 7, 1994

Current Labeling

Operation Manual

Auto Syringe® AS40A

Model AS40A Infusion Pump



Baxter

TABLE OF CONTENTS

About This Manual	1
Device Description	2
Precautions	3
Special Precautions for Epidural Administration	6
Simplified Instructions	7
Programming	7
Operation	9
Programming The Continuous Infusion Modes	10
Programming The Timed Infusion Modes	11
General Device Information	13
Technical Specifications	13
The LCD Panel	14
The Keypad	16
The Status Panel	17
Operating States	18
Standby State	18
Run State	18
Data Display and Entry	19
Drug Library Option	20
Infusion Modes	21
Syringe Data Tables	23
Infusion Rate Ranges	23
Deliverable Volumes	24
Detailed Instructions	25
Preliminary Operations	25
Manual Prime	25
Mount the Syringe	25
Turn the Pump On	27
Check the Lamp Test Display	27
Programming	28
Using the Optional Drug Library	28
"mL/hr" Mode Programming	28
"U/hr" Mode Programming	30
"Single Dose" Mode Programming	31
"Manual Schedule" Mode Programming	33
"Auto Schedule" Mode Programming	35
"mcg/min" Mode Programming	36
"mcg/kg/min" Mode Programming	37
General Programming Information	38
Active Fields	38
Editing in Standby State	39

TABLE OF CONTENTS

Editing in Run State	40
Edit Cancellation	40
Number Out of Range	40
Data Test	41
Expanded Data Display	41
Additional Functions and Operations	42
Purge Operation	42
Purge Delivery Table	43
Bolus Operation	44
Bolus Units	44
Bolus Size Limits	44
Bolus Rate Limits	45
Bolus Programming	45
Bolus Programming Notes	45
Bolus Delivery	46
Bolus Delivery Notes	46
Bolus Review and Editing	46
Repeating a Bolus Delivery	46
Changing the Syringe	47
Lock and Auto Lock Functions	48
The Total Delivered Field	48
Configuration	49
Configuration Review	49
Configurable Options	50
Terminating Configuration Review	54
Custom Configuration	54
Standard Configuration	55
Charging the Battery	56
I.V. Pole Clamp	57
IV Pole Loop	58
Pump Maintenance	59
Cleaning	59
Daily Check	60
Keypad Check	60
Mechanical Check	61
Display Check	61
In Case of Difficulty	62
Alert and Alarm Displays	63
Error Responses	64
Alerts	66
Alarms	68

TABLE OF CONTENTS

Failsafe Alarms	70
Warranty	71
Service Information	72
INDEX	- i -



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JAN 7 1994

73

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About This Manual

This edition of the AS40A Operation Manual pertains to pumps with and without the Drug Library Option. This manual is intended for use by trained healthcare professionals, familiar with infusions and infusion pump procedures.

Notation used in this manual:

" ... " (quotes) In addition to the normal grammatical usage, quotes are used to differentiate names from units of measure.

For example, "mL/hr" refers to the name of an operating mode, whereas mL/hr is a unit of measure.

[...] (square brackets) Denote text prompts as they appear on the LCD panel.

For example, [ML/HR] is the exact text that appears on the bottom line of the LCD when selecting the "mL/hr" mode.

<...> (angle brackets) Enclose data exactly as entered on the keypad.

For example, <123><CONFIRM> means: "press the keys 1, 2, and 3, and then press the key labeled 'confirm'."

(hh:mm) Signifies that the left two digits represent hours, and the right two digits represent minutes.

Text boxes are used to highlight information pertaining to the Drug Library option.



IMPORTANT: Read and understand all operating instructions and the "Alerts and Precautions" section of this manual before using the AS40A Infusion Pump.

Device Description

The AS40A Infusion Pump is designed to meet the fluid and drug delivery requirements of today's changing clinical environment. It provides for accurate continuous or intermittent infusion via intravenous (IV), intra-arterial (IA), epidural, or subcutaneous routes of administration.

The AS40A accepts standard disposable syringes from 1 mL to 60 mL in size. A numeric keypad simplifies programming and makes the pump easier to use. Safety and effectiveness are reinforced by pre-programmable bolus operation, titration of a dose without interruption of fluid flow, and easily understood alarm and alert messages.

The AS40A can be custom configured for the healthcare facility. This allows an institution or clinic to select those key features which meet specific requirements. Configurable options include: Drug Library feature, syringe manufacturer, automatic syringe size recognition, selectable infusion modes, maximum infusion rates, occlusion pressure sensitivity, and keypad auto lock. The selected options can be reviewed easily by the user and the chosen configuration can be changed to meet new or different requirements.

The AS40A can run on its internal rechargeable battery pack and can also be operated while attached to a battery charger.

The AS40A is supplied with a pole clamp and a built-in IV pole loop. The pump can also be used as a table-top unit.



Precautions



Federal (USA) law restricts this device to sale by or on the order of a physician.



The charger port is to be used only with "900 Series" chargers or other accessories that are labeled specifically for use with the AS40 Series Infusion Pumps.



CAUTION: No user serviceable parts inside. Refer all service, repair, and calibration to qualified technical personnel.



CAUTION: Do not operate the AS40A with or without a battery charger in the presence of flammable anesthetics, oxygen-enriched, or explosive atmospheres.

- Though the factory-supplied configuration settings are suitable for most therapies, the operator and hospital professionals should verify that the pump's settings are appropriate for the clinical application.
- The Drug Library is a configuration option developed to facilitate pump infusion setup for individual patients based upon input from clinical users. Before using the Library for any specific drug, refer to the full prescribing information supplied by the drug manufacturer.
- As with all medical electronic equipment, care must be exercised to avoid exposing this device to powerful sources of electromagnetic interference. This device design has been tested to the requirements of MDS-201-0004, and to applicable portions of MIL-STD-461C, Part 4, which are voluntary test guidelines for electromagnetic susceptibility and emissions. This device was not found to be adversely affected by the susceptibility tests in these specifications, and will perform safely. The device's emissions were also found to be acceptable.
- Do not expose the pump to X-rays, gamma rays, or other ionizing radiation, or to strong electric or magnetic fields.
- Do not autoclave, steam sterilize, ETO sterilize, or subject the AS40A Infusion Pump or charger to temperatures in excess of 45 °C (113 °F).
- Do not use hard or sharp objects on the keypad.

Precautions

- If a [LINE OCCLUDED] alarm occurs, RELIEVE THE RESIDUAL PRESSURE IN THE SYRINGE BY RELEASING THE PLUNGER DRIVER. If the pressure is not relieved prior to clearing the occlusion, an unintentional small bolus may occur when the blockage is cleared. Check for kinked tubing, clogged catheter, etc. Check for foreign material preventing movement of the pump mechanism.
- Be sure to PURGE THE SYSTEM OF ALL AIR BEFORE ADMINISTERING ANY MEDICATION. Failure to follow this normal infusion procedure could precipitate serious consequences.
- Remember that the volume of fluid contained in the connecting tubing is a residual amount and cannot be infused. Allow for this needed extra volume of fluid when initially filling the syringe.
- In Manual Schedule mode, <START> must be pressed to deliver each dose and continue the infusion regimen. Pressing any other key silences the audio alarm and leaves the pump in Standby state, without initiating a dose delivery.
- Although extreme care has been taken in assembly, component selection, and quality control during manufacture of Auto Syringe® pumps, routine procedures must be adhered to so that patients receiving medications can be assured of trouble-free operation.
- Caution must be exercised in the selection of drugs intended to be delivered via any infusion pump. If the drug contained in the syringe will be exposed to significant environmental conditions for prolonged time periods, IT IS IMPORTANT TO SELECT DRUGS THAT WILL NOT CHANGE PHARMACOLOGICALLY UPON SUCH EXPOSURE.
- As with all automatic infusion devices, whenever a TOXIC OR DANGEROUS LEVEL of drug is stored in the reservoir, CONSTANT MONITORING of the infusion is required.
- CAUTION must be employed to assure that your Auto Syringe® infusion pump is in good working order before putting it into use. If the pump is being operated on battery power alone, check to be sure that the battery has been charged as described in this manual.

- When the pump is first turned on, verify that the Lamp Test is accurate (see "Daily Check" section, page 60).
- Verify all program data before pressing <START>.
- Wipe off spills immediately. Do not allow fluid or residues to remain on the pump.
- Silent Running is a configurable option, available only in Single Dose mode, that silences the audio portion of the [<10 MIN EMPTY] alert and the [DOSE COMPLETE] alarm. This option is only recommended for infusions that are constantly monitored by a health care provider or by electronic instrumentation.
- If the SIZE OVERRIDE configuration option is enabled, an operator can manually override the Syringe Recognition feature. Incorrect syringe information may cause delivery errors.

Repeated incorrect identification of syringe size by Syringe Recognition may signify a pump fault condition, or that a syringe manufacturer has made a dimensional change. The pump should be removed from service as soon as possible, so that the problem can be investigated.



Special Precautions for Epidural Administration

- **Epidural administration of anesthetics is limited to short-term infusion (not to exceed 96 hours) with indwelling catheters specifically indicated for short-term anesthetic epidural drug delivery.**
- **Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short- or long-term analgesic epidural drug delivery.**
- **To prevent infusion of drugs that are not indicated for epidural use, do not use administration sets that incorporate injection sites during epidural delivery.**
- **It is strongly recommended that pumps used for epidural drug delivery be clearly differentiated from pumps used for other routes of administration:**
- **WARNING: Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.**

Simplified Instructions

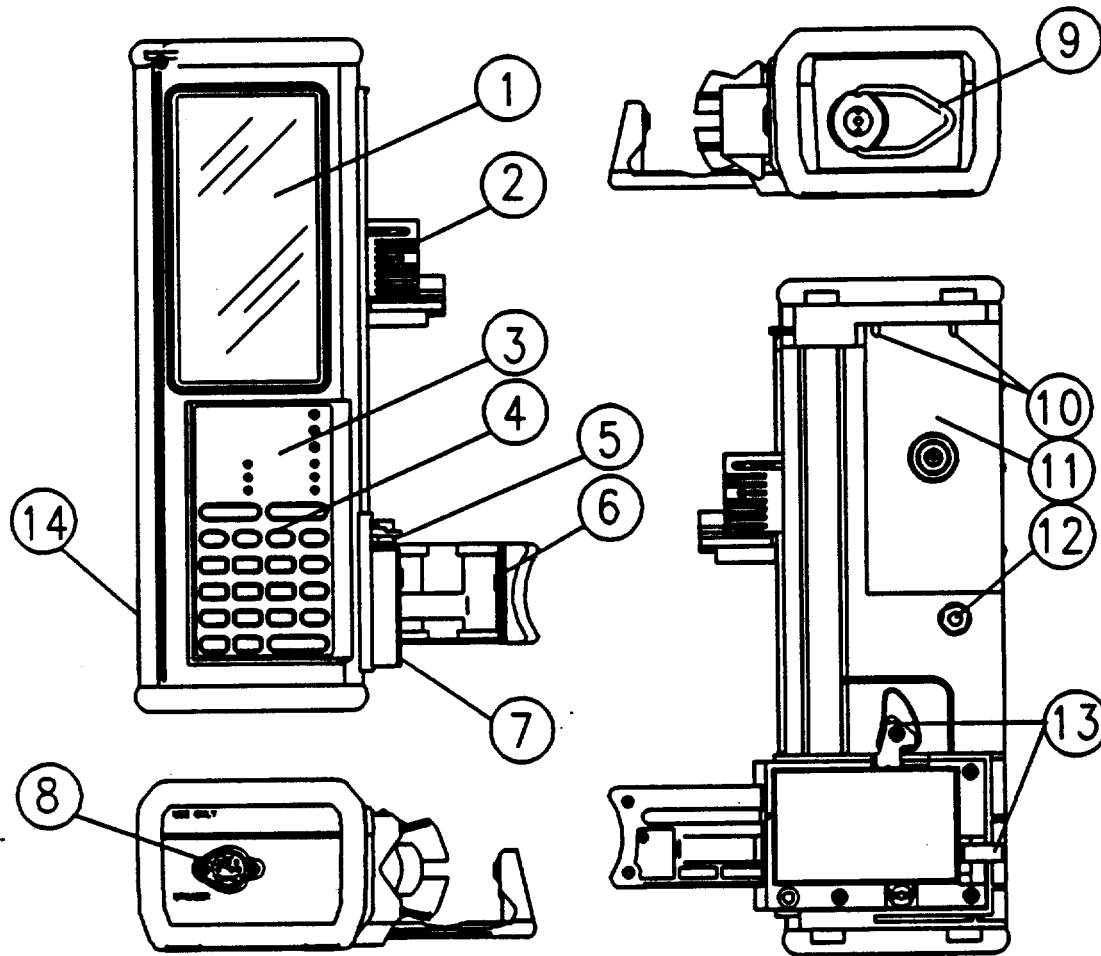
Programming

- 1) At the [SELECT MODE ▼▲] prompt, use <▼> or <▲> to step through the modes. Press <CONFIRM> to select the delivery mode.

If the Drug Library is installed, then at the [SELECT DRUG ▼▲] prompt, use <▼> or <▲> to step through the drug list. Press <CONFIRM> to select the drug.

- 2) Select syringe manufacturer and size, using <▲> or <▼> keys and <CONFIRM>.
- 3) Enter data as required.
 - ▶ The "active" field is the one that is flashing.
 - ▶ Use <▲>, <▼>, or number keys to display the desired value.
 - ▶ Press <CONFIRM> to enter the number.
- 4) Changing programmed data:
 - ▶ Use <▲> or <▼> key to move to the desired field.
 - ▶ Press <EDIT> key. The present number flashes.
 - ▶ Use <▲>, <▼>, or number keys to change the value.
 - ▶ Use <CONFIRM> key to enter the new number.
- 5) To program or edit the bolus size:
 - ▶ Press <BOLUS><EDIT>.
 - ▶ Set bolus size, using <▲>, <▼>, or number keys as required.
 - ▶ Press <START> to deliver bolus, or <CONFIRM> to store the bolus size.
- 6) To clear the TOTAL field:
 - ▶ Use <▲> or <▼> to select the TOTAL field.
 - ▶ Press <EDIT><CLR> to reset the total volume to [0.00].

Simplified Instructions



Refer. Num.	DESCRIPTION	Refer. Num.	DESCRIPTION
1	LCD Panel	8	Charger Port (I/O Port)
2	Plunger Assembly (Finger Grip, Plunger Clamp, Driver)	9	IV Pole Loop
3	Status Panel	10	Pole Clamp Mounting Pins
4	Keypad	11	Battery Cover
5	Tab Slot	12	Pole Clamp Attach Recess
6	Barrel Clamp	13	Barrel Clamp Release Levers
7	Cradle	14	ON/OFF Switch

Handwritten signature

Operation

- 1) Attach the IV set to the syringe and manually purge the filled syringe and tubing.
- 2) Mount the syringe on the pump.
 - ▶ Pull out the plunger driver (2), slide to top of the pump, and release.
 - ▶ Release barrel clamp (6), using lever (13) on side or rear of pump.
 - ▶ Place syringe in cradle (7), making sure the flange fits into the slot (5).
 - ▶ Close the barrel clamp (6) firmly against the syringe.
 - ▶ Pull out the plunger driver (2), slide down, capture top of syringe plunger, and release.
- 3) Turn the ON/OFF switch (14) to the "on" position.
- 4) Program the pump.
 - ▶ Use the arrow keys as needed to select the syringe and infusion regimen.

If the Drug Library is installed, use the arrow keys as needed to select the drug name, concentration, syringe, and infusion regimen.

 - ▶ Enter additional program data as prompted, using <CONFIRM> after each selection.
- 5) Purge the syringe and tubing.
 - ▶ Press <PURGE> <START> to begin purging. Repeat if necessary. Press <STOP> if necessary to stop purging.
- 6) Press <START> to begin the infusion.

Programming The Continuous Infusion Modes

"mL/hr"	"Units/hr"	"mcg/min"	"mcg/kg/min"
Select Mode, syringe mfr, syringe size	Select Mode, syringe mfr, syringe size	Select Mode, syringe mfr, syringe size	Select Mode, syringe mfr, syringe size
			Enter patient body weight in kg.
	Enter drug concentration in Units per mL (U/mL).	Enter drug concentration in mg/mL.	Enter drug concentration in mg/mL.
Enter infusion rate in mL/hr	Enter the dose in Units per hour (U/hr)	Enter the dose in mcg/min	Enter the dose in mcg/kg/min
Enter the volume limit (mL)			
Enter bolus size in mL	Enter bolus size in Units	Enter bolus size in mg	Enter bolus size in mcg/kg
PURGE the system	PURGE the system	PURGE the system	PURGE the system
Press <START>	Press <START>	Press <START>	Press <START>

NOTES:

- 1) U/hr = Units per hour mL = milliliters kg = kilograms
mg = milligrams mcg = micrograms
- 2) Each mode is normally programmed in the sequence shown, in top-to-bottom order.
- 3) If the Drug Library is installed and active, these modes can be accessed directly by selecting [GENERAL] from the Drug Library.
- 4) The concentration is automatically entered when using a selection from the Drug Library. The concentration can be edited if the selected drug is configured as "Variable".

Programming The Timed Infusion Modes

Single Dose	*Manual Schedule*	*Auto Schedule*
Select Mode, syringe mfr, syringe size	Select Mode, syringe mfr, syringe size	Select Mode, syringe mfr, syringe size
Enter Dose Size (INFUSE) in mL	Enter Dose Size (INFUSE) in mL	Enter Dose Size (INFUSE) in mL
Enter Dose Duration (OVER) in hours and minutes (hh:mm)	Enter Dose Duration (OVER) in hours and minutes (hh:mm)	Enter Dose Duration (OVER) in hours and minutes (hh:mm)
	Enter Dose Interval (EVERY) in hours and minutes (hh:mm)	Enter Dose Interval (EVERY) in hours and minutes (hh:mm)
	Enter Dose Delay (NEXT DOSE IN) in hours and minutes (hh:mm)	Enter Dose Delay (NEXT DOSE IN) in hours and minutes (hh:mm)
PURGE the system	PURGE the system	PURGE the system
Press <START>	Press <START>	Press <START>
	When the DOSE DUE alarm sounds, press <START> to deliver one dose.	

NOTES:

- 1) U/hr = Units per hour mL = milliliters kg = kilograms
 mg = milligrams mcg = micrograms hr = hours
 min = minutes
- 2) Each mode is normally programmed in the sequence shown, in top-to-bottom order.
- 3) If the Drug Library is installed and active, these modes can only be accessed by selecting [GENERAL] from the Drug Library.

Simplified Instructions

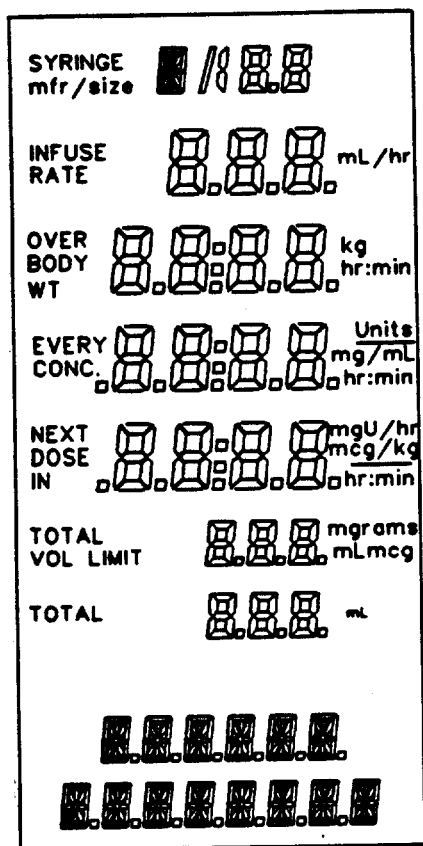
WLF

General Device Information

Technical Specifications

Model:	AS40A Infusion Pump.
Catalog Code:	<ul style="list-style-type: none">● 1M8565 = with Drug Library Option● 1M8560 = without Drug Library Option (upgradable to 1M8565).
Size:	approx. 3.4" x 2.6" x 10" (8.6 x 6.7 x 25 cm)
Weight:	approx. 2.75 lbs. (1.25 kg)
Accuracy:	+/- 3% (not including syringe tolerance) For volume infusions: +/- 3%, or .007" of travel, whichever is greater (not including syringe tolerance).
Syringes:	B-D Plastipak®, 1, 3, 5, 10, 20, 30, 60 mL Monoject®, 1, 3, 6, 12, 20, 35, 60 mL Terumo®, 1, 3, 5, 10, 20, 30, 60 mL
Flow Rate Range:	0.01 mL/hr to 360 mL/hr (dependent on syringe size).
Deliverable Volume:	The full syringe volume can be delivered.
Data Display:	Self-prompting, multi-field LCD (Liquid Crystal Display)
Status Display:	Nine-LED (Light Emitting Diode) array
Power Requirement:	<ul style="list-style-type: none">● AC: 105-125V 60 Hz (battery charger)● DC: internal nickel-cadmium battery pack
Battery Life:	12 hours of operation at 2 mL/hr using a 60 mL syringe, following a 16 hour charge.
Temperature Range:	0 °C to 45 °C (32 °F to 113 °F) Note: Delivery of high viscosity fluids at low temperatures is not recommended.
Keypad:	Elastomeric type, with tactile feedback.
Construction:	High-impact plastic case with removable elastomeric protective bumpers. Water resistant.

The LCD Panel



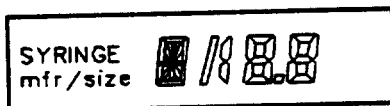
The LCD (Liquid Crystal Display) has eight information areas, called "fields". Except for the text field at the bottom, each field displays three types of information:

- 1) The words on the left side of each field, called "annunciators", identify the type of data contained in the field.
- 2) The central portion of each field displays variable numeric data, either decimal numbers or time. This data generally represents either infusion program information or an active display such as a running total of the amount of drug infused.
- 3) The annunciators on the right side show the applicable units of measure.

The bottom field of the LCD is a two-line text display, used to prompt the programming sequence or to display a message about the infusion.

After the operating mode has been selected, the pump automatically displays the necessary fields to be programmed. When information is needed, the pump prompts by flashing the "active" field.

General Device Information

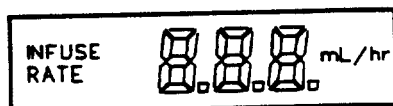


Field #1 displays the syringe manufacturer code and syringe size in mL.

[B] = B-D®

[T] = Terumo®

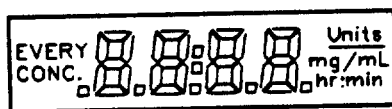
[M] = Monoject®



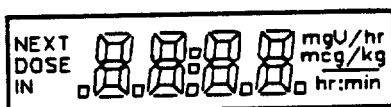
Field #2 displays the quantity to be infused (mL), or the infusion rate (mL/hr).



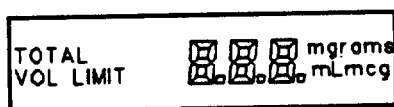
Field #3 displays dose duration (hh:mm), or patient body weight (kg).



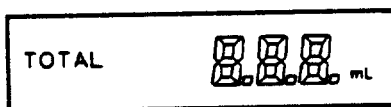
Field #4 displays dose interval (hh:mm), drug concentration (mg/mL, or Units/mL), or the bolus size (Units or mL).



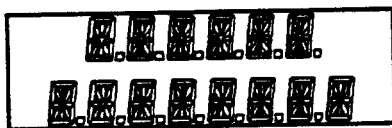
Field #5 displays the time remaining until the next dose is due (hh:mm), the dose size (mcg/min, mcg/kg/min, or Units/hr), or the bolus size (mg or mcg/kg).



Field #6 displays the total delivered (mL, mcg, mg, or grams), volume limit (mL), or bolus size (mL).



Field #7 displays the total amount that has been delivered (mL).



Field #8 displays a multitude of text prompts and messages.

Handwritten signature

The Keypad

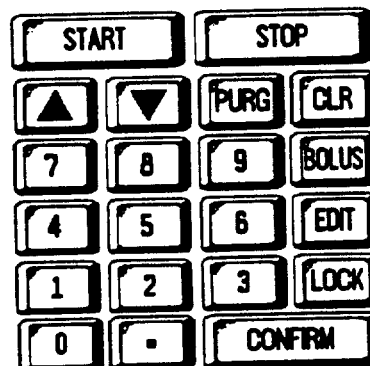
The keypad includes a standard decimal numeric keypad ("digit keys"), up and down arrow keys, and various function keys.

Arrow Keys



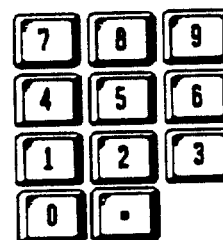
The UP arrow (▲) key increases a number or moves to the next field.

The DOWN arrow (▼) key decreases a number or moves to the previous field.



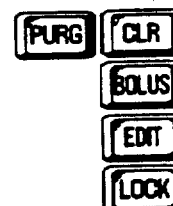
Digit Keys

The calculator-type numeric keypad is used to directly enter numeric values.



Function Keys

The five function keys (<PURGE>, <CLR>, <BOLUS>, <EDIT>, <LOCK>) perform specific tasks or activate specific functions.



Action Keys

<START> and <STOP> begin and end actions.



The <CONFIRM> key is used to complete a step, to accept a prompt, or to display additional infusion program information.



The Status Panel

RUN lights

The pump is in Run state when any of the green RUN lights are on.

When the three green RUN lights flash in sequence (called a "falling drop" pattern), the pump is infusing.

When only the top RUN light is flashing, the pump is counting time until an infusion is to begin.

All three RUN lights flash simultaneously during a bolus or purge.

ALERT

The red ALERT light flashes during an alert or alarm, to indicate that operator attention is necessary. The front panel and status lights may display additional information.

BATTERY

When flashing, the red BATTERY light indicates that the battery charge is low. If the battery becomes significantly discharged, the BATTERY light stays on constantly and the pump goes into a "Failsafe Alarm" state.

ON CHARGE

When on, the green ON CHARGE light indicates that the battery charger is plugged in.

STANDBY

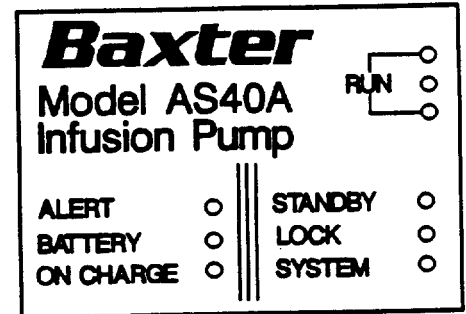
The yellow STANDBY light flashes to indicate that the pump is in Standby state.

LOCK

When on, the yellow LOCK light indicates the keypad is locked.

SYSTEM

The red SYSTEM light indicates that there is something wrong with the pump. The pump cannot operate until the problem is corrected. The infusion must be reprogrammed.



Operating States

Standby State

When the pump is in Standby state, the infusion is stopped and the yellow STANDBY light begins to flash. If the pump is left in Standby state, a "Pump Is Idle" alert or alarm occurs.

Run State

There are two Run states: Run Delivering state and Run Counting state.

In Run Delivering state, the infusion program is running and the pump is delivering an infusion. The three green RUN lights sequence in a "falling drop" pattern.

In Run Counting state, the top RUN light flashes. The infusion program is counting time until the next dose is due, and the pump is not delivering an infusion.

Note: Bolus and Purge operations are special infusion states. The RUN lights flash in unison when bolusing or purging.



Data Display and Entry

Numeric Data	Numbers are displayed in a right-justified format. A leading zero is supplied when the field size permits. <div>For example, the value ".12" is displayed as [0.12].</div>
Time Data Fields	While entering hours and minutes, the digits are displayed right registered. Leading zero(es) are automatically supplied if needed. <div>For example, 1 minute is entered by pressing <1>, <CONFIRM> and is displayed as [0:01].</div>
Automatic Decimal	If a number is entered without a decimal point, the pump automatically places a decimal point to the right of the number when the <CONFIRM> key is pressed.
Flashing the Data	The data within a field flashes to show that the field has been "opened" and is ready to be programmed or edited.
Flashing Annunciators	The annunciators for the "active" field flash. The "active" field will be opened when <EDIT> is pressed.
Data Test	All data is tested when it is entered (by pressing <CONFIRM>). If the entered value is too large or too small, the [PUMP LIMIT] error message will be displayed, a short audio beep will sound, and the pump will substitute the <u>nearest acceptable value</u> . Press the <CONFIRM> key to accept the new value, or else enter a different value.
Key Clicks	The audio makes a sound when a key is pressed. An invalid keypress elicits a short "beep" sound. Simultaneous keypresses are ignored.
Extended Data Display	While an infusion is in progress, pressing <CONFIRM> displays additional information for a few seconds, then automatically resumes the normal display.

Drug Library Option

Each pump with the Drug Library Option is provided with a Drug Library Chart, which summarizes the available drug library selections and delivery parameters. The Drug Library Option is a "list" of drug-specific infusion parameters that are stored in the AS40A memory.

Each drug selection in the Drug Library includes preset infusion parameters, including:

- Drug Name (abbreviated if necessary, to fit the display)
- Drug Concentration (Fixed or Variable)
- Drug Infusion Mode(s) (e.g. mcg/kg/min)

Some drugs have more than one available infusion mode. If so, then the next prompt after selecting the drug is [SELECT MODE ▼▲].

The Drug Library selection [GENERAL] allows access to all infusion modes (e.g. "mL/hr", "Units/hr", etc.).

The bolus infusion rate is specific to each drug. For some drugs, the bolus rate is also determined by the patient body weight.

When the Drug Library has been installed, it can be turned on (enabled) or turned off (disabled) by means of the pump configuration procedure. This procedure can be done on-site, and is described in the "AS40A Infusion Pump Technical Manual".

The Drug Library is a configuration option developed to facilitate pump infusion setup for individual patients, based upon input from clinical users. Before using the Library for any specific drug, refer to the full prescribing information supplied by the drug manufacturer.

Infusion Modes

The AS40A can deliver in seven modes, which fall into two major categories: "timed" and "continuous" infusions. Timed infusions deliver one or more equal doses according to a programmed schedule. Continuous infusions deliver at a steady, programmed rate. Each of these modes are briefly described below. For additional information, see the "Detailed Instructions" section of this manual.

"mL/hr" Mode

In "mL/hr" mode, the pump is programmed for a continuous infusion. The rate of infusion is programmed in milliliters per hour (mL/hr).

"Units/hr" Mode

In "Units/hr" mode, the pump is programmed for a continuous infusion. The drug concentration is entered in Units per milliliter (Units/mL), and the rate of infusion is entered in Units per hour (U/hr).

"Single Dose" Mode

In "Single Dose" mode, the pump is programmed to infuse a single dose over a specified period of time. The dose is entered in milliliters (mL), and the time period is entered in hours and minutes (hh:mm).

"Manual Schedule" Mode

In "Manual Schedule" mode, the pump is programmed to infuse a dose over a specified period of time, and to **repeat** the dose at specified intervals. The dose is entered in milliliters (mL), and the time period and interval are entered in hours and minutes (hh:mm).

The pump alerts the user when a dose is due to start, and the user must press **<START>** to initiate each dose.

"Auto Schedule" Mode

In "Auto Schedule" mode, the pump is programmed to infuse a dose over a specified period of time, and to repeat the infusion at specified intervals. The dose is entered in milliliters (mL), and the time period and interval are entered in hours and minutes (hh:mm).

Whereas "Manual Schedule" mode requires the user to press <START> to initiate each dose, "Auto Schedule" mode automatically starts each dose when it is due.

"mcg/min" Mode

In "mcg/min" mode, the pump is programmed for a continuous infusion. The drug concentration is entered in milligrams per milliliter (mg/mL), and the rate of infusion is entered in micrograms per minute (mcg/min). The pump automatically displays the effective rate in milliliters per hour (mL/hr).

"mcg/kg/min" Mode

In "mcg/kg/min" mode, the pump is programmed for a continuous infusion. The patient's body weight is entered in kilograms (kg), the drug concentration is entered in milligrams per milliliter (mg/mL), and the rate of infusion is entered in micrograms per kilogram of body weight per minute (mcg/kg/min). The pump automatically displays the effective rate in milliliters per hour (mL/hr).

Syringe Data Tables

These tables represent the performance ranges for infusion delivery parameters which are a function of the syringe dimensions.

Infusion Rate Ranges

Syringe Manufacturer	Syringe Size (mL)	Minimum Flow Rate (mL/hr)	Maximum Flow Rate (mL/hr)
B-D®	1	0.01	10
	3	0.02	30
	5	0.03	50
	10	0.1	100
	20	0.1	150
	30	0.1	200
	60	0.1	360
Monoject®	1	0.01	10
	3	0.02	30
	6	0.03	50
	12	0.1	100
	20	0.1	150
	35	0.1	200
	60	0.1	360
Terumo®	1	0.01	10
	3	0.02	30
	5	0.03	50
	10	0.1	100
	20	0.1	150
	30	0.1	200
	60	0.2	360

The "Maximum Rate" information in this table applies to pumps configured for Rate Range = High.

Rate Range = Medium limits the maximum rate to 120 mL/hr. Rate Range = Low limits the maximum rate to 10 mL/hr.

Deliverable Volumes

Syringe Manufacturer	Syringe Size (mL)	Minimum Volume (mL)	Maximum Volume (mL)
B-D®	1	0.03	1.0
	3	0.07	3.0
	5	0.11	5.0
	10	0.3	10
	20	0.4	20
	30	0.5	30
	60	0.8	60
Monoject®	1	0.03	1.0
	3	0.07	3.0
	6	0.11	6.0
	12	0.3	12
	20	0.4	20
	35	0.5	35
	60	0.8	60
Terumo®	1	0.03	1.0
	3	0.07	3.0
	5	0.11	5.0
	10	0.3	10
	20	0.4	20
	30	0.5	30
	60	0.8	60

This table shows the minimum and maximum programmable settings for bolus, volume limit, single dose, and scheduled dose deliveries.

Detailed Instructions

This section is a detailed description of the six basic steps required to operate the AS40A Infusion Pump:

- 1) Attach the IV set to the syringe and manually purge the filled syringe and associated tubing.
- 2) Mount the syringe on the pump.
- 3) Turn the "ON/OFF" switch on, and check pump operation.
- 4) Program the infusion.
- 5) Purge the syringe and tubing.
- 6) Press <START> to begin the infusion.

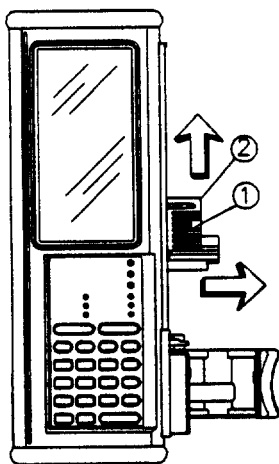
At the operator's option, the infusion may be programmed before mounting the syringe on the pump.

Preliminary Operations

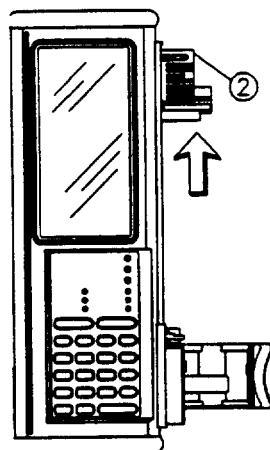
Manual Prime

Attach the infusion set to the filled syringe. Remove the sterile cap. Manually prime until a drop of fluid is visible at the end of the tubing. Replace the sterile cap on the end of the tubing.

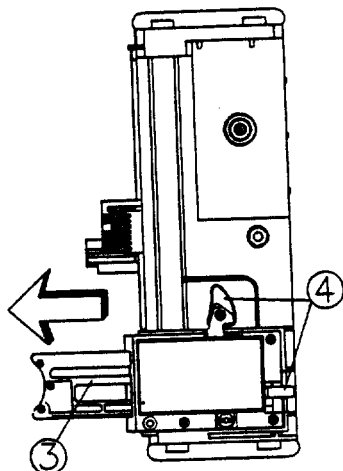
Mount the Syringe



- 1) Grasp the FINGER GRIP (1) on the DRIVER (2) and lift it all the way out.

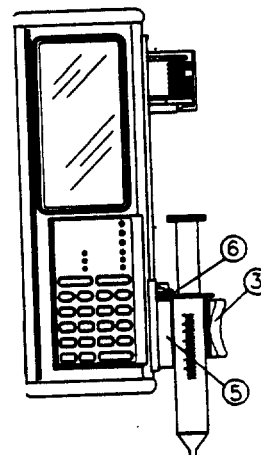


- 2) Slide the DRIVER to the top of the pump and release the FINGER GRIP.

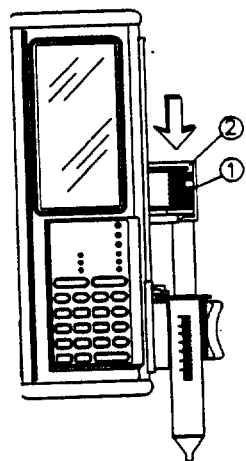


- 3) Open the BARREL CLAMP (3) by moving either of the BARREL CLAMP RELEASE LEVERS (4). Allow the clamp to slide all the way open.

- 4) Place the syringe in the CRADLE (5). Make sure the syringe is centered in the "V" of the cradle, and that the finger tab of the syringe fits into the TAB SLOT (6). Push the BARREL CLAMP (3) in firmly, so that it securely grips the syringe barrel. The barrel clamp is shaped to fit the heel of the hand, making it easier to firmly clamp the syringe.



Note: If the Syringe Detection feature is enabled, a [CHECK SYRINGE] message occurs when the syringe barrel is not centered in the clamp, or when the syringe finger tab (also called a "flange") is not captured by the TAB SLOT.



- 5) Grasp the FINGER GRIP (1) on the DRIVER (2) and lift it all the way out. Slide the DRIVER down until it contacts the syringe plunger, then release.

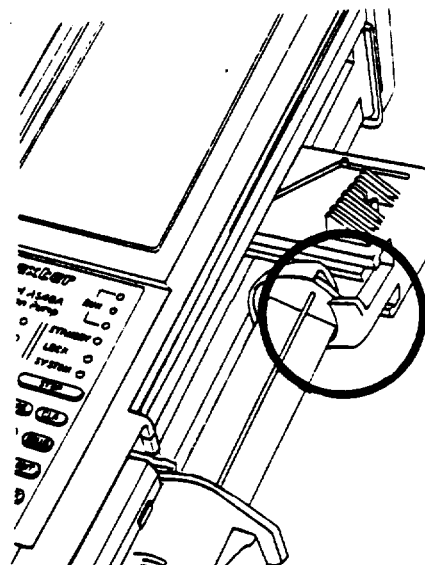
60

- 6) **Be sure the PLUNGER CLAMP captures the syringe plunger.**

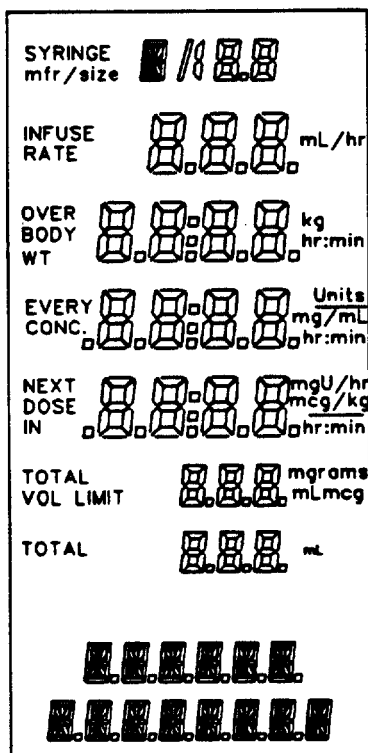
Turn the Pump On

The ON/OFF switch is on the left side of the pump, near the bottom. Turn the pump on by moving the switch up to the ON position.

The pump is turned off by moving the switch down to the OFF position.



Check the Lamp Test Display



As soon as the pump is turned on, it begins an automatic self-test. This includes a "Lamp Test" which turns on the LCD. Check to ensure that all the lights illuminate and that all parts of the LCD are legible. The AS40A Lamp Test display should be carefully checked daily or once per shift. See "Daily Check", Page 60.

To examine the LCD more closely during the Lamp Test, press and hold <STOP> while the LCD characters are all turned on (visible). The Lamp Test will complete after the <STOP> key is released.

The Lamp Test ends with a short beep. If the pump is configured to show an identifier message, it will appear at this time in the text display field (Field #8) at the bottom part of the LCD.

At the conclusion of the Lamp Test, the LCD will display either: [SELECT MODE ▼▲], or [SELECT DRUG ▼▲], depending on whether the Drug Library Option has been

installed and enabled. Use either arrow key to step through the available selections, then press <CONFIRM>.

The AS40A is ready for programming an infusion when the preliminary operations have been completed.

Programming

For additional information about programming the AS40A, refer to the section titled "General Programming Information", page 38.

Using the Optional Drug Library

Each drug selection in the Drug Library is pre-configured to allow selection and programming of only the infusion modes best suited for delivery of that particular drug.

Many Drug Library selections allow only one delivery mode. When one of these selections is made at the [SELECT DRUG ▼▲] prompt, the pump will automatically select the delivery mode.

Some Drug Library selections allow several delivery modes. When one of these selections is made at the [SELECT DRUG ▼▲] prompt, the pump will follow with [SELECT MODE ▼▲]. Use either arrow key to step through the available mode selections, then press <CONFIRM>.

Refer to the appropriate delivery mode programming instructions, below.

"mL/hr" Mode Programming

If the Drug Library is installed and active, selecting [GENERAL] results in the [SELECT MODE ▼▲] prompt.

In "mL/hr" mode, the pump runs at a programmed, constant rate. There are three basic programming steps:

- 1) From the [**SELECT MODE ▼▲**] prompt, use <▼> or <▲> to step through the mode selection menus. Select "mL/hr" mode by pressing <**CONFIRM**> when the [**ML/HR**] message appears.
- 2) Use the <▼> or <▲> and <**CONFIRM**> keys as required to select syringe manufacturer and size.
- 3) Enter the infusion rate in mL/hr. Press <**CONFIRM**> to lock in the number.

Volume Limit

The Volume Limit feature is a configurable option, and is available only in "mL/hr" mode. The pump stops delivering when the programmed volume limit has been delivered.

Enter the desired volume limit at the [**ENTER VOL LIM**] prompt. Once the delivery begins, the VOL LIMIT field will display the amount of drug remaining until the programmed volume limit is reached. The pump stops when the VOL LIMIT field reaches zero.

For a single infusion, this feature can be disabled without reconfiguring the pump by programming zero [0] in the Volume Limit field.

Bolus In "mL/hr" Mode

If the infusion program is to include a bolus delivery, press <**BOLUS**> to obtain the bolus programming display. Press <**EDIT**>, then use <▼>, <▲>, or the digit keys to set the bolus size (in mL). Press <**CONFIRM**> to store the bolus size and return to the normal display. The bolus infusion rate is automatically set. See "Bolus Operation", page 44, for more information on bolus delivery.

"mL/hr" Programming Notes:

- 1) In a facility that uses only one or two syringe manufacturers, programming can be simplified by configuring the pump to prompt only for the syringe brand(s) actually used.
- 2) See "Syringe Data Tables", page 23, for minimum/maximum delivery parameters for each syringe.

- 3) Pressing **<CONFIRM>** during delivery briefly displays additional program data.

"U/hr" Mode Programming

If the Drug Library is installed and active, selecting **[GENERAL]** results in the **[SELECT MODE ▼▲]** prompt.

Units per hour ("U/hr") mode is a continuous infusion mode similar to "mL/hr" mode, except that the infusion is programmed by entering drug concentration and dose.

- 1) Select "U/hr" mode, syringe manufacturer, and syringe size using the **<▼>**, **<▲>** and **<CONFIRM>** keys, as previously described.
- 2) Enter the drug concentration (CONC.) in Units per mL (Units/mL). Press **<CONFIRM>** to lock in the number.
- 3) Enter the dose rate in Units per hour (U/hr). Press **<CONFIRM>** to lock in the number. The pump automatically calculates and displays the equivalent rate in mL/hr.

Bolus in "U/hr" Mode

In "U/hr" mode, bolus programming is similar to the procedure used in "mL/hr" mode, except that the bolus size is entered in Units and automatically converted to mL. Bolus rate is displayed in mL/hr. See "Bolus Operation", page 44, for more information on bolus delivery.

"U/hr" Programming Notes

- 1) The drug concentration range is from 0.01 Units/mL to 9999 Units/mL. The dose limits are determined by the drug concentration and syringe size. See "Syringe Data Tables", page 23, to find the maximum and minimum delivery rates for each syringe.
- 2) The CONC. field cannot be reprogrammed once the infusion has been started.

- 3) Pressing **<CONFIRM>** during delivery briefly displays additional program data.

If the Drug Library is installed and active, some drug selections may be configured for "fixed" concentration. The concentration cannot be altered when one of these drugs is selected.

"Single Dose" Mode Programming

If the Drug Library is installed and active, selecting **[GENERAL]** results in the **[SELECT MODE ▼▲]** prompt.

"Single Dose" mode delivers a programmed volume of drug (in mL) over a specified period of time. Bolus delivery is not available in this mode.

- 1) Select "Single Dose" mode, syringe manufacturer, and syringe size using the **<▼>**, **<▲>** and **<CONFIRM>** keys, as previously described.
- 2) Enter the dose volume (INFUSE) in mL. Press **<CONFIRM>** to lock in the number.
- 3) Enter the dose duration (OVER) in hours and minutes (hh:mm). All time displays use standard time notation: the two digits to the left of the colon show hours, the two digits to the right show minutes.
- 4) The pump will issue a **[DOSE COMPLETE]** alarm at the end of the infusion.

Silent Running

Silent Running is a configurable option that is available only in "Single Dose" mode. If Silent Running is enabled, the audio beeper will not sound when the **[<10 MIN EMPTY]** alert or the **[DOSE COMPLETE]** alarm occurs. **This option is only recommended for infusions that are constantly monitored by a health care provider or by appropriate instrumentation.**

"Single Dose" Programming Notes

- 1) The placement of the colon in the OVER field is fixed. This means that one or two trailing zeroes may need to be entered as "space holders", to make sure that the programmed time is correct.
- 2) If the INFUSE or OVER fields are edited, the pump will treat the result as a new infusion. As a reminder, [DOSE CANCELED] will appear for a few seconds.
- 3) If the TOTAL field is edited, the pump will not treat the result as a new infusion.

For Example:

- Program the pump to infuse 5 mL over 5 minutes, using a B-D 30 mL syringe. Stop the infusion when the "TOTAL mL" field shows that about 2 mL have been delivered. Now edit the "OVER" field to 6 minutes (note that [DOSE CANCELED] appears for a few seconds), and start the infusion. When the pump stops after 6 minutes, about 7 mL will have been delivered; 2 mL from the original infusion, and 5 mL from the edited infusion. When a "Single Dose" infusion program is edited, it is then treated as a new infusion.
- Turn the pump off, then back on and program the same infusion (5 mL over 5 minutes, B-D 30 mL syringe). Stop the infusion after about 2 mL have been delivered. This time, edit the "TOTAL mL" field by clearing it to [0.00]. Then restart the infusion. Note that when <START> is pressed, the message [DOSE RESUMES] is briefly displayed. When the pump stops, the "TOTAL mL" field will display about 3 mL. If the "TOTAL mL" field is edited, the pump does not treat the result as a new infusion.

- 4) Pressing <CONFIRM> during the delivery will briefly display the syringe, the delivery rate in mL/hr, and the operating mode.
- 5) Bolus operation is not available in this delivery mode.

"Manual Schedule" Mode Programming

If the Drug Library is installed and active, selecting [GENERAL] results in the [SELECT MODE ▼▲] prompt.

Manual Schedule operation is a timed infusion mode consisting of a programmed dose that is to be repeated at regular intervals. The dose is first programmed in mL over time (hours and minutes), and then the timer is set to sound an alarm when each dose is due. "Manual Schedule" mode also includes a first-dose delay, allowing a time delay before the infusion regimen begins.

Note that each dose delivery must be manually initiated in Manual Schedule operation.

- 1) Select "Manual Schedule" mode, syringe manufacturer, and syringe size using the <▲>, <▼>, and <CONFIRM> keys.
- 2) Enter the dose (INFUSE) in mL. Note that each dose will be the same size. Press <CONFIRM>.
- 3) Enter the dose duration (OVER) in hours and minutes, then press <CONFIRM>. This is the amount of time to infuse one dose.
- 4) Enter the interval (EVERY) in hours and minutes, then press <CONFIRM>. This is the time from the start of one dose to the start of the next dose.
- 5) Enter the delay (NEXT DOSE IN), then press <CONFIRM>. This is the time interval from when <START> is pressed until the first dose becomes due. Enter [0:00] to begin infusing the first dose immediately.

Dose Due

Field #5 (NEXT DOSE IN), shows the time remaining until the next dose is due to be delivered. When this time counts down to [0:00], the pump signals that the dose is due by flashing the **ALERT** and **STANDBY** lights, sounding continuous audio beeps, and showing [DOSE DUE] in the text field.
<START> MUST BE PRESSED TO BEGIN INFUSING EACH DOSE.

When a dose is due, pressing any key other than **<START>** silences the audio, turns off the **[DOSE DUE]** prompt and **ALERT** light, and leaves the pump in Standby state, but does NOT begin dose delivery. **<START>** MUST BE PRESSED TO BEGIN INFUSING EACH DOSE.

"Counting Time" Display

The three green **RUN** lights flash in a "falling drop" pattern while the pump is infusing. When the pump is counting time between scheduled doses, only the top **RUN** light flashes.

"Manual Schedule" Programming Notes

- 1) Bolus operation is not available in this delivery mode.
- 2) For all Manual Schedule infusion regimens, it is recommended that the "Idle Alarm" feature be enabled (configured), and that the "Auto Lock" feature be disabled (not configured).
- 3) The programmed delivery can be stopped at any time by pressing **<STOP>**. The green **RUN** light(s) then turn off, the yellow **STANDBY** light begins flashing, and the **TOTAL mL** field stops counting up. Press **<START>** to continue the program.
- 4) Pressing **<STOP>** affects the NEXT DOSE IN time field in several different ways, depending on the pump's infusion status at the time:
 - If **<STOP>** is pressed while the pump is infusing a dose (the three **RUN** lights flashing in sequence), the NEXT DOSE IN field will stop counting down, until **<START>** is pressed again. This feature allows the schedule to be delayed while ensuring delivery of the full dose.
 - If **<STOP>** is pressed while the pump is counting down the time to the next dose (only the top **RUN** light flashes), the NEXT DOSE IN field will continue to count down while the pump is stopped. This feature allows editing during idle time, without altering the overall schedule.
 - If a dose becomes due while the pump is stopped, the delivery will begin immediately when **<START>** is pressed.

- 5) Pressing **<CONFIRM>** during the delivery displays the syringe, the delivery rate (RATE) in mL/hr, the time until next dose (NEXT DOSE IN), the total delivered (TOTAL) and the operating mode.

Precaution: In Manual Schedule mode, **<START>** must be pressed to deliver each dose and continue the infusion regimen. Pressing any other key silences the audio alarm and leaves the pump in Standby state, without initiating a dose delivery.

"Auto Schedule" Mode Programming

If the Drug Library is installed and active, selecting **[GENERAL]** results in the **[SELECT MODE ▼▲]** prompt.

Auto (Automatic) Schedule operation functions very much like Manual Schedule, except that each dose delivery begins automatically when the NEXT DOSE IN timer reaches **[0:00]**. It is not necessary to press **<START>** to begin delivery of each dose. When each dose is due, the pump will deliver the dose automatically.

"Auto Schedule" Programming Notes

- 1) "Auto Schedule" mode programming and operation is identical to Manual Schedule mode, except that dose delivery is automatically initiated.
- 2) Bolus operation is not available in this mode.
- 3) Pressing **<CONFIRM>** during the delivery displays the syringe, the delivery rate (RATE) in mL/hr, the time until next dose (NEXT DOSE IN), the total delivered (TOTAL) and the operating mode.



"mcg/min" Mode Programming

If the Drug Library is installed and active, selecting [GENERAL] results in the [SELECT MODE ▼▲] prompt.

In "mcg/min" operation, the pump runs at a programmed, constant rate. This is similar to "mL/hr" mode, except that the infusion is programmed in terms of drug concentration.

- 1) Select "mcg/min" mode, syringe manufacturer, and syringe size, using the <▲>, <▼>, and <CONFIRM> keys.
- 2) Enter the drug concentration (CONC.) in milligrams per milliliter (mg/mL). Press <CONFIRM> to lock in the number.

If programming a Drug Library selection, the drug concentration (CONC.) appears automatically.

- 3) Enter the dose in micrograms per minute (mcg/min). Press <CONFIRM> to lock in the number.

Bolus In "mcg/min" Mode

In "mcg/min" mode, the bolus size is programmed in milligrams (mg). The pump automatically calculates the equivalent bolus size in milliliters (mL), and displays both quantities when the bolus display is activated. See "Bolus Operation", page 44, for more information on bolus delivery.

"mcg/min" Programming Notes

- 1) After the DOSE field is programmed, the pump automatically calculates and displays the equivalent delivery rate in milliliters per hour (mL/hr).
- 2) The CONC. field cannot be edited (reprogrammed) if the infusion has been started and any amount of drug has been delivered.

If programming a Drug Library selection that is configured for "fixed" concentration, the CONC. is automatically programmed, and cannot be edited (reprogrammed).

- 3) The concentration range is from .0001 to 100.0 milligrams per milliliter (mg/mL).
- 4) A bolus can only be programmed, edited, or delivered after the drug concentration (CONC.) has been programmed.
- 5) Pressing <CONFIRM> during delivery briefly displays additional program data.

"mcg/kg/min" Mode Programming

If the Drug Library is installed and active, selecting [GENERAL] results in the [SELECT MODE ▼▲] prompt.

In "mcg/kg/min" operation, the pump runs at a programmed, constant rate. This is similar to "mcg/min" operation, except that the infusion is programmed in terms of both drug concentration and patient body weight.

- 1) Select "mcg/kg/min" mode, syringe manufacturer, and syringe size, using the <▲>, <▼>, and <CONFIRM> keys.
- 2) Enter the patient body weight (BODY WT) in kilograms (kg). Press <CONFIRM> to lock in the number.
- 3) Enter the drug concentration (CONC.) in milligrams per milliliter (mg/mL). Press <CONFIRM> to lock in the number.

If programming a Drug Library selection, the drug concentration (CONC.) appears automatically.

- 4) Enter the dose (DOSE) in micrograms per kilogram of patient body weight per minute (mcg/kg/min).

Bolus In "mcg/kg/min" Mode

In mcg/kg/min operation, the bolus size is programmed in micrograms per kilogram of patient body weight (mcg/kg). The pump calculates the equivalent delivery in milliliters (mL), and displays both quantities when the bolus display is activated. See "Bolus Operation", page 44, for more information on bolus delivery.

"mcg/kg/min" Programming Notes

- 1) After the dose (DOSE) is programmed, the pump automatically calculates and displays the equivalent delivery rate in milliliters per hour (mL/hr).
- 2) The CONC. and BODY WT. fields cannot be reprogrammed once an infusion has been started.

If programming a Drug Library selection that is configured for "fixed" concentration, the CONC. field is automatically programmed, and cannot be edited (reprogrammed) at any time.

- 3) The concentration range is from .0001 to 100.0 milligrams per milliliter (mg/mL). The concentration range may be further limited for very large or small body weights. The patient body weight range is from 0.01 to 200.0 kilograms (kg).
- 4) A bolus can only be programmed, edited, or delivered after the drug concentration (CONC.) has been programmed.
- 5) Pressing <CONFIRM> during delivery briefly displays additional program data.

General Programming Information

Active Fields

The AS40A uses flashing annunciators (the words to the right and left of each field) to show which field is "active". Use the <▼> and <▲> arrow keys to

change the "active" field to the next LCD field. Press **<EDIT>** to "open" the "active" field, so that it can be edited.

Editing in Standby State:

Almost every programmable field can be changed (edited) before a bolus or infusion has been started. The exceptions are:

- The drug concentration (CONC.) field cannot be edited when using a Drug Library selection that is configured for "fixed" concentration.
- Once the delivery mode and drug (if the Drug Library feature is active) have been selected, the only way to select a different drug or delivery mode is to shut the pump off, then turn it back on and reprogram.

The drug concentration (CONC.) and patient body weight (BODY WT) fields cannot be changed (edited) once an infusion or bolus has been delivered.

The procedure for editing program data differs according to whether the data has been "locked in" by pressing the **<CONFIRM>** key:

- **PRIOR TO** pressing **<CONFIRM>**, the data can be changed by simply pressing **<CLR>** and re-entering the new value.
- **AFTER** pressing **<CONFIRM>**, the data can only be edited after all remaining fields have been programmed. Then:
 - 1) Use the **<▼>** **<▲>** (arrow keys) to step to the field in need of change.
 - 2) Press **<EDIT>**, use **<▼>**, **<▲>**, **<CLR>**, and digit keys as necessary to enter the new value, and press **<CONFIRM>** to complete the action.

For Example:

- Select ML/HR mode, and program a B-D 60 mL syringe. The RATE field now shows flashing dashes. Key in **<100>**, but do not press **<CONFIRM>**.
- Press **<CLR>**. The RATE field clears to dashes, because the number [100] had not been locked in by pressing **<CONFIRM>**.

Editing In Run State

The RATE and DOSE fields can be **edited** while the infusion is running. This allows "fine tuning" of the infusion without interruption of drug delivery.

The TOTAL field can be **cleared** while the infusion is running. Note that the TOTAL field is a data display, and cannot be edited.

Edit Cancellation

If a field is open for editing, pressing **<EDIT>** will restore the previous value. The pump will display **[EDIT CANCELED]** for a few seconds.

For Example:

- Select ML/HR mode, and program a B-D® 60 mL syringe. Enter **<99>** in the RATE field and a volume limit of 60 mL.
- The RATE field annunciators now flash to show it is currently the "active" field. Pressing **<CLR>** only results in an "invalid key" alert.
- Press **<EDIT>**. Key in another valid number.
- Press **<EDIT>** again. This will "undo" the change, restore the previous value (**[99]**), and display **[EDIT CANCELED]**.

Number Out of Range

Every programmable field is limited to a particular range of allowed program values, depending on the syringe, drug concentration, and other factors. An attempt to program a value outside the acceptable range will result in a **[PUMP LIMIT]** error response. The pump will then beep and substitute the nearest acceptable value. Press **<CONFIRM>** to accept the value, or press **<CLR>** and then program a new value.

There is a certain expected range of program values for each Drug Library selection. The pump issues a precautionary message if a program value outside this normal range is entered. The precautionary messages are explained in the "Alert and Alarm Displays" section of this manual.

Data Test

Whenever a data field is edited, the pump tests the remaining program data fields for range limits. If there is a conflict, the affected fields are cleared to dashes, and the first cleared field is automatically opened for editing. As each cleared field is reprogrammed, the next cleared field if any, is automatically opened. All cleared fields must be reprogrammed before the infusion can be started.

For Example:

Reprogramming the "SYRINGE mfr" field automatically clears the "SYRINGE size" field.

Expanded Data Display

During an infusion, the LCD generally displays only the most important infusion information. Pressing the <CONFIRM> key temporarily shows additional program information. Press <CONFIRM> again to restore the normal display immediately. If no key is pressed the normal display will automatically resume in a few seconds.

Additional Functions and Operations

Purge Operation

The AS40A "Purge Operation" function advances the syringe plunger driver a preset distance. The primary purpose of this function is to eliminate slack in the drive mechanism and thus ensure prompt fluid delivery when the infusion is started. To prevent unintended delivery to the patient, the tubing **must not** be connected to the patient while purging.

The "Purge Volume" shown in the Purge Delivery Table (next page) represents the nominal amount of drug that would be delivered in one complete Purge Operation cycle, if there were no slack in the drive system. This information is useful for calculating the excess fluid allowance when filling the syringe.

The Purge Operation can be stopped before the pump completes a full cycle. Manual purge followed by a Purge Operation is recommended whenever a syringe is mounted on the pump, prior to any connection to the patient.

Purge operation is allowed only when the pump is in Standby state.

Purge Procedure

- 1) After programming the pump, press **<STOP>** (if necessary), to put the pump in Standby state.
- 2) Press **<PURGE>**. The normal display is temporarily replaced by a display showing the purge rate in milliliters per hour (mL/hr), and the message **[PURGE READY]**.
- 3) Press **<START>** to begin delivering the fixed purge volume. Note: If **<START>** is not pushed within 10 seconds, the purge operation will be canceled and the pump will revert to Standby State.

The display will show **[PURGE RUNNING]** while the purge operation is in progress, then the normal Standby state display will be restored, and the text field will read **[PURGE COMPLETE]** for a few seconds.

- 4) Repeat steps (2) and (3) as often as necessary to obtain a steady drip at the end of the tubing.

- 5) Purge operation delivers a fixed volume of fluid. If a steady drip of fluid is observed before the full purge volume is delivered, purge operation can be stopped immediately by pressing <STOP>.

Purge Delivery Table

Syringe Manufacturer	Syringe Size (mL)	Approximate Purge Volume (mL)	Purge Rate (mL/hr)
B-D®	1	0.02	10
	3	0.08	30
	5	0.16	50
	10	0.23	100
	20	0.39	150
	30	0.50	200
	60	0.76	360
Monoject®	1	0.02	10
	3	0.09	30
	6	0.17	50
	12	0.27	100
	20	0.45	150
	35	0.60	200
	60	0.76	360
Terumo®	1	0.02	10
	3	0.09	30
	5	0.18	50
	10	0.27	100
	20	0.44	150
	30	0.58	200
	60	0.91	360

Notes:

- The purge rates shown here apply to pumps configured for Rate Range "H".
- Purge volumes are approximately the amount that would be delivered in a single complete purge operation, without slack in the drive system.
- The volume of purged fluid is not added to the amount displayed in the "Total Delivered" field.
- During purge operation, all three RUN LEDs flash simultaneously.

Bolus Operation

A bolus is a fixed dose which may be programmed and delivered, either during an infusion or while the pump is in Standby state.

Bolus Units

Infusion Mode	Bolus Size Units
mL/hr	mL (milliliters)
Units/hr	Units
Single Dose	Bolus operation not available
Manual Schedule	Bolus operation not available
Automatic Schedule	Bolus operation not available
mcg/min	mg (milligrams)
mcg/kg/min	mcg/kg (micrograms of drug per kilogram of patient body weight)

Bolus Size Limits

The minimum programmable bolus size is approximately the same as the minimum deliverable volume (see "Syringe Data Tables", page 23).

The maximum programmable bolus size is the lesser of:

- The syringe size (the entire syringe may be programmed as a single bolus).
- 9999 Units, or 9999 mg, or 9999 mcg/min (whichever units are applicable).

Certain combinations of drug selection, patient body weight, bolus size, and drug concentration may result in a [BOLUS > (drug max)] or a [BOLUS < (drug min)] message. See page 67.

Bolus Rate Limits

In general, the bolus infusion rate is the same as the maximum infusion rate shown in the "Syringe Data Tables", page 23.

Certain combinations of drug selection, patient body weight, and drug concentration may limit the bolus infusion rate to a lower value.

Bolus Programming

- 1) Press the **<BOLUS>** key. The LCD changes to the Bolus display.
 - If there is no programmed bolus size, the text field will read **[PRESS EDIT TO SET BOLUS SIZE]**. Proceed to step (2).
 - If a bolus size has been programmed, the text field will read **[BOLUS READY]**. Press **<START>** within 10 seconds to begin bolus delivery, or proceed to step (2) to change the programmed bolus size.
- 2) Press **<EDIT>**, then use the **<▲>**, **<▼>**, **<CLR>**, and digit keys as necessary to program the bolus size.
- 3) Press **<START>** to begin bolus delivery immediately, or press **<CONFIRM>** to save the bolus size and return to the normal display.

Bolus Programming Notes

- Pressing **<BOLUS>** during the **[BOLUS READY]** or **[PRESS EDIT TO SET BOLUS SIZE]** display restores the normal display immediately.
- A bolus can be programmed and delivered from Standby state, even when the infusion has not been fully programmed. The minimum program data required for bolus operation are: Syringe mfr/size, drug concentration (if applicable), and body weight (if applicable).
- If there is insufficient program information for bolus operation, the text display will show **[DATA MISSING]** when **<BOLUS>** is pressed.



Bolus Delivery

During bolus delivery, the text display reads [**BOLUS RUNNING**] and all three RUN LEDs flash simultaneously.

- 1) To halt bolus delivery before the full bolus amount has been delivered, press **<STOP>**. This restores the normal display, and the text field will read [**BOLUS STOPPED**] for a few seconds.
- 2) If the pump is allowed to deliver the full bolus amount, then the normal display and operating state will be automatically restored. The text field will read [**BOLUS COMPLETE**] for a few seconds.

Bolus Delivery Notes

- During bolus delivery, the display will show the amount that has been bolused.
- If a bolus is delivered during an infusion, the infusion will resume automatically once the bolus delivery ends. If the bolus delivery is stopped prematurely by pressing **<STOP>**, the pump displays [**DOSE RESUMES**] for a few seconds.
- The bolus volume is added to the "Total Delivered" display after the bolus operation stops.

Bolus Review and Editing

Press the **<BOLUS>** key to review the bolus size. The bolus information will be displayed for about 10 seconds, or the normal display can be restored immediately by pressing **<BOLUS>** or **<CONFIRM>**.

A bolus may be programmed or edited during an infusion, without interrupting normal delivery. Bolus editing follows the same rules as initial bolus programming.

Repeating a Bolus Delivery

To repeat a bolus, first press **<BOLUS>** to display the bolus size, then press **<START>**.

Changing the Syringe

An empty syringe may be replaced when the pump is in the Standby state. If a different syringe size is used, the syringe size must be reprogrammed. The programming steps required to accomplish this task depend on whether the Syringe Recognition feature has been enabled (configured).

- If Syringe Recognition **is enabled**, the syringe size can be edited while the pump is stopped, but there may be several additional prompts:
 - 1) The pump will automatically display [VERIFY (name)]. ("name" refers to the syringe manufacturer).
 - 2) Use <▲>, <▼>, and <CONFIRM> to select the correct syringe manufacturer.
 - 3) The pump will then check the syringe size and display [VERIFY xx ML] (where "xx" represents the syringe size).
 - 4) Verify that the syringe size is correct by pressing <CONFIRM>. Note: if the wrong syringe size is displayed, refer to "In Case of Difficulty", page 62.
- If Syringe Recognition **is not enabled**, the syringe size can be edited while the pump is stopped:
 - 1) Press <▲> or <▼> until the Field #1 annunciator (SYRINGE mfr/size) flashes.
 - 2) Press <EDIT> to begin the editing process.
 - 3) Use <▲>, <▼>, and <CONFIRM> as needed to select the correct syringe manufacturer.
 - 4) Use <▲>, <▼>, and <CONFIRM> as needed to select the correct syringe size.

Note that changing syringe size may invalidate the contents of other fields (e.g. VOL LIMIT). In such cases, the pump will automatically clear the necessary field(s). The infusion cannot be continued until all cleared fields have been reprogrammed.



Lock and Auto Lock Functions

The Lock function serves two purposes. First, it reduces risk of accidental key activations by disabling all keys except <LOCK>. Second, by disabling the audio portion of the "Pump is Idle" alert, the Lock function allows the pump to be programmed in advance of delivery.

After the infusion has been programmed, the Lock function can be activated by pressing the <LOCK> key. Pressing <LOCK> again restores normal operation. The yellow LOCK light remains on while the Lock function is active.

The AS40A Auto Lock feature can be enabled through pump configuration, as part of the "Misc" group. The Auto Lock feature automatically sets the Lock function two minutes after the last keypress, instead of activating a "Pump is Idle" alert. See page 68.

The Total Delivered Field

The Total Delivered field displays the accumulated total volume (in mL) that has been delivered. Some delivery modes also show the total delivery in other units such as mcg or mg. Either or both of the bottom data fields (Fields #6 and #7) may be used to display Total Delivered data.

TOTAL	000	mg
VOL LIMIT	000	mLmcg
TOTAL	000	mL

The Total Delivered field cannot be programmed, but can be cleared (reset to zero). Use the <▲> or <▼> arrow key until the "Total Delivered" display field annunciators flash, then press <EDIT><CLR> to clear the field. After resetting the Total Delivered field to zero, the previous value cannot be restored.

Purge volumes are not included in the total, because purged fluid is not intended to be infused into the patient.

If the accumulated total becomes too large to display (i.e. over 999 mL), the field will show [EEE].

Configuration

The AS40A infusion pump can be custom-configured to "tailor" each pump to meet particular needs, or to simplify infusion programming.

Configuration Review

The AS40A Configuration Review feature allows the pump's configuration to be examined without risk of accidental alteration. This feature is activated by entering the code number **<123>** at the initial prompt (**[SELECT MODE ▼▲]** or **[SELECT DRUG ▲▼]**). Ignore the "Invalid Key" beeps that occur when entering the code.

The configurable options are organized into several groups, each of which begins with a prompt that requires a "yes" or "no" response. Each option category is identified by name in the text display field, followed by a question mark (for example: **[VIEW MODES ?]**). The upper text field displays a **[Y]** (for "yes"), which represents the pending response.

Press **<CONFIRM>** to accept the pending response, and begin reviewing the options within that category. The text field will display only the options that are configured. Pressing **<CONFIRM>** steps to the next option. When the last option in a category has been displayed, the next category prompt is displayed (for example: **[VIEW MFRS?]**).

To skip a category, press either **<▲>** or **<▼>** to change the **[Y]** to **[N]** (for "no"), indicating that review of this category is not wanted, and press **<CONFIRM>** to advance the screen to the next category.

For Example:

To review the "Modes" group, the initial prompt is **[VIEW MODES?]**. Answering **[Y]** (the default response) opens up that group for review. Answering **[N]** skips that group and prompts for the "manufacturers" group (**[VIEW MFRS?]**).

The table on the next page shows the configuration group headings, and the configurable selections within each group. Note that inactive features and selections are not shown in Configuration Review mode.



Configuration

AS40A Configuration Review Tree Access code: <123>			
GROUP PROMPT	GROUP SELECTIONS		
[VIEW DRUGS?]	Pumps With Drug Library: List of configured drugs. Pumps Without Drug Library: [GENERAL] or [NONE DEFINED]		
[VIEW MODES?]	ML/HR UNITS/HR	SINGLE DOSE MANUAL SCHEDULE	AUTO SCHEDULE MCG/MIN MCG/KG/MIN
[VIEW MFRS?]	B-D	MONOJECT	TERUMO
[VIEW DFAULTS?]	DRUG DEFAULT MFR DEFAULT	MODE DEFAULT SYRING DEFAULT	
[VIEW MISC?]	DRUG LIBRARY SYRING RECOGNIT SIZE OVERRIDE	PSI RANGE RATE RANGE AUDIO RANGE AUTO LOCK	VOLUME LIMIT SILENT RUNNING IDLE ALARM

Configurable Options

The option categories are listed here and in the table above, in the order in which they appear during Configuration Review. Note: the terms "enabled" and "configured" are both used to signify that an option has been selected or activated by appropriate pump configuration settings.

Drugs ([VIEW DRUGS?])

This option category displays the configured drugs, one at a time. Refer to the Drug Library chart, provided with the Drug Library Option, for a complete list of drugs.

Within the "View Drugs" group, drugs that are configured for **variable** concentration will be displayed by name only. Drugs configured for **fixed** concentration will display the concentration in addition to the name.

Modes ([VIEW MODES?])

This option category lists the infusion modes that are configured. Each listing shows only the mode name (e.g [ML/HR]) in the text field. There are seven infusion modes: "mL/hr", "Units/hr", "Single Dose", "Manual Schedule", "Auto Schedule", "mcg/min", and "mcg/kg/min".

Most Drug Library selections are restricted to use with a limited set of infusion modes. When the Drug Library Option is enabled and a drug is selected, all infusion modes appropriate to that Drug Library selection will be available, regardless of pump configuration.

For Example:

Mivacurium ([MIVACURI]) can only be infused in "mcg/kg/min" mode. Selecting this drug automatically enables "mcg/kg/min" mode, whether or not it was enabled as a configuration option.

Syringe Manufacturers ([VIEW MFRS?])

This option category displays the syringe manufacturers (brands) that are configured. The available options are: B-D®, Monoject®, and Terumo®.

Defaults ([VIEW DFAULTS?])

This option category displays the "default" options that are configured. The AS40A allows four "default" options: [DRUG DEFAULT], [MODE DEFAULT], [MFR DEFAULT], [SYRING DEFAULT]. The defaults enable the pump to "remember" the selection that was used for the previous infusion, and to provide that selection in response to the first <▼> or <▲> keypress. This feature is especially useful when a particular drug, mode, or syringe is used frequently.

Miscellaneous ([VIEW MISC?])

This option category displays the "miscellaneous" options that are configured. The "miscellaneous" group options are: Drug Library, Syringe Recognition, Syringe Detection, Size Override, Occlusion Sensitivity (PSI Range), Audio Range, Rate Range, Auto Lock, Volume Limit, Silent Running, and Idle Alarm.

Drug Library ([DRUG LIBRARY])

This configuration setting determines whether the Drug Library will be available to the operator (enabled). See also "Drug Library Option", page 20.



Syringe Recognition ([SYRING RECOGNIT])

After a syringe has been mounted and the manufacturer has been programmed, Syringe Recognition automatically identifies and displays the syringe size. This simplifies programming, and reduces opportunity for operator error.

Size Override ([SIZE OVERRIDE])

This feature allows the operator to instruct the pump to accept a syringe size other than the size identified by Syringe Recognition. The arrow keys are used to alter the displayed size, then the operator is prompted to press <CONFIRM> several times to verify the change.

Precaution: If the SIZE OVERRIDE configuration option is enabled, an operator can manually override the Syringe Recognition feature. Incorrect programming of syringe information may cause delivery errors.

Repeated incorrect identification of syringe size by Syringe Recognition may signify a pump fault condition, or that a syringe manufacturer has made a dimensional change. The pump should be removed from service as soon as possible, so that the problem can be investigated.

Syringe Detection ([SYRING DETECT])

Syringe Detection is a safety feature that issues an alert or an alarm if the syringe is improperly mounted in the barrel clamp. Syringe Detection is automatically enabled when Syringe Recognition is configured.

Occlusion Sensitivity ([PSI RANGE])

The PSI Range option sets the occlusion detection system operating range. Three choices are available: H = High (highest backpressure), M = Medium, L = Low (lowest backpressure).

Audio Range ([AUDIO RANGE])

The audio beeper level can be configured for normal ([H]=high) or quiet ([L] =low) volume level. The recommended setting is [H]=high. The quiet setting should only be used in noise-sensitive environments where the infusion is constantly monitored.

Rate Range ([RATE RANGE])

The Rate Range option limits the maximum delivery rate to the lesser of:

- 1) The syringe maximum (see "Infusion Rate Ranges" table, page 23),
- or 2) 360 mL/hr ("H"), 120 mL/hr ("M"), or 10 mL/hr ("L").

The minimum delivery rate is as shown in the "Rate Ranges" table, regardless of the Rate Range setting.

Auto Lock ([AUTO LOCK])

If an infusion has been programmed, the Auto Lock feature automatically turns on the Lock function two minutes after the last keypress.

Volume Limit ([VOLUME LIMIT])

This feature operates in "mL/hr" mode only. The Volume Limit feature triggers an alarm after the pump has delivered a programmed amount of drug.

This feature also issues an alert when the Volume Limit will be reached within ten minutes of delivery, at the current infusion rate.

Silent Running ([SILENT RUNNING])

The Silent Running configuration option can only be used in Single Dose mode. This feature silences the audio portion of the [**<10 MIN EMPTY**] / [**<10 MIN (drug name)**] alert and the [**DOSE COMPLETE**] alarm.

Precaution: This option is only recommended for infusions that are constantly monitored by a health care provider or by electronic instrumentation.

Idle Alarm ([IDLE ALARM])

When the Idle Alarm feature is **enabled** (configured as [Y]), the occurrence of a [**PUMP IS IDLE**] alert will cause the pump to beep continuously. When the Idle Alarm feature is **disabled** (configured as [N]), the occurrence of a [**PUMP IS IDLE**] alert will cause the pump to beep 15 times, every 2 minutes.



Identifier

The Identifier is not a Configuration Review option, but is included here for reference purposes. The identifier is a short message (up to 8 characters) that is displayed for three seconds following the Lamp Test. The Identifier can be created or edited during the pump configuration process. The available characters include the letters A-Z, the numerals 0-9, the dash (-), and the space character.

Terminating Configuration Review

When the last "Miscellaneous" option has been reviewed, the pump automatically restarts the Lamp Test, as if it had just been turned on.

To cancel Configuration Review at any time, simply turn the pump off.

Custom Configuration

The AS40A can be reconfigured as often as desired, to select features that best suit the needs of the healthcare facility.

If there is any question regarding the pump's current configuration or applicability for a particular clinical application, the operator and healthcare professionals should verify that the settings are appropriate.

While no special tools are needed, the configuration can be changed only by designated personnel.



Standard Configuration

The factory standard configuration is:

► Drugs:

Pumps with Drug Library Option (1M8565): Some of the Drug Library selections are configured as "fixed" or "variable" concentration. The remaining selections are not enabled.

Drug selections configured as "fixed" are displayed with a concentration (CONC.) value. Those configured as "variable" are displayed without a concentration (CONC.) value.

Pumps without Drug Library Option (1M8560): Only [GENERAL] is available. [GENERAL] is disabled (N).

► Modes:

ML/HR	= (Y) enabled	UNITS/HR	= (Y) enabled
SINGLE DOSE	= (Y) enabled	MANUAL SCHEDULE	= (Y) enabled
MCG/KG/MIN	= (Y) enabled	AUTO SCHEDULE	= (Y) enabled
MCG/MIN	= (Y) enabled		

► Manufacturers:

B-D®	= (Y) enabled	Monoject®	= (Y) enabled
Terumo®	= (Y) enabled		

► Defaults:

DRUG DEFAULT	= (Y) enabled	MODE DEFAULT	= (N) disabled
MFR DEFAULT	= (N) disabled	SYRINGE DEFAULT	= (N) disabled

► Misc:

DRUG LIBRARY		AUDIO RANGE	= (H) high
1M8565 pumps	= (Y) enabled	RATE RANGE	= (H) high
1M8560 pumps	= (N) disabled	AUTO LOCK	= (N) disabled
SYRINGE RECOGNITION	= (Y) enabled	VOLUME LIMIT	= (Y) enabled
SYRINGE DETECTION	= (Y) enabled	SILENT RUNNING	= (N) disabled
SIZE OVERRIDE	= (N) disabled	IDLE ALARM	= (Y) enabled
PSI RANGE	= (M) medium		

► Identifier: none

Charging the Battery

The battery charger cord plugs into the bottom of the pump.

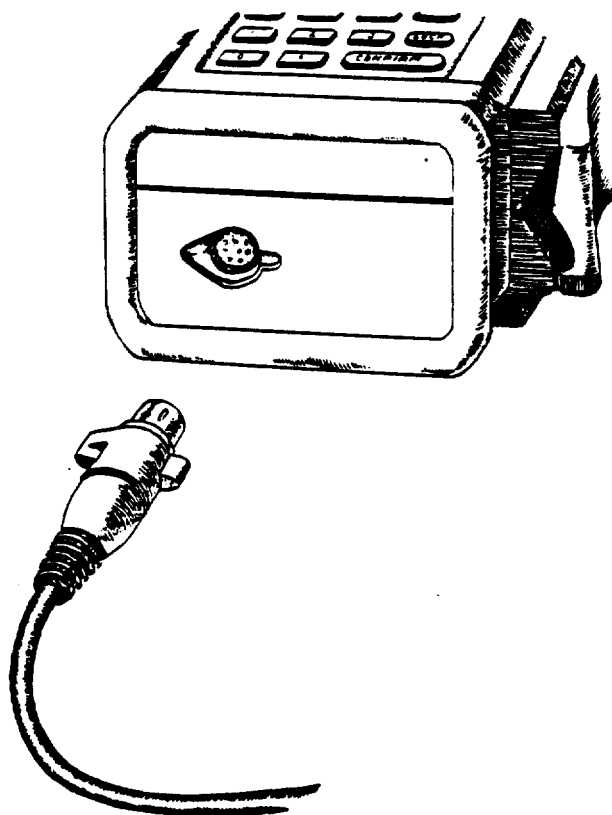
Note that the plug and receptacle are shaped to fit only one way. DO NOT force the plug into place.

For best battery life, the battery should be charged for at least 16 hours before using the pump. Disconnect the charger if the pump is not to be used within the next 48 hours. Prolonged overcharge and high temperature shorten the battery service life.

Do not charge or store the pump in direct sunlight, or under excessively warm conditions.

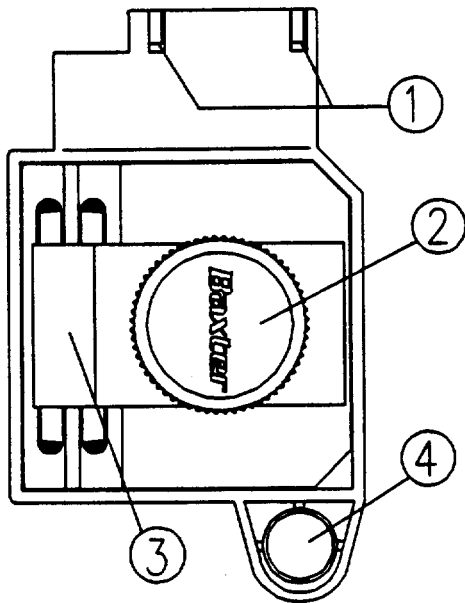


Use only "900 Series" chargers or other accessories that are labeled specifically for use with AS40 Series Infusion Pumps. The standard battery charger (USA) is Model #C-AS40-01-900.



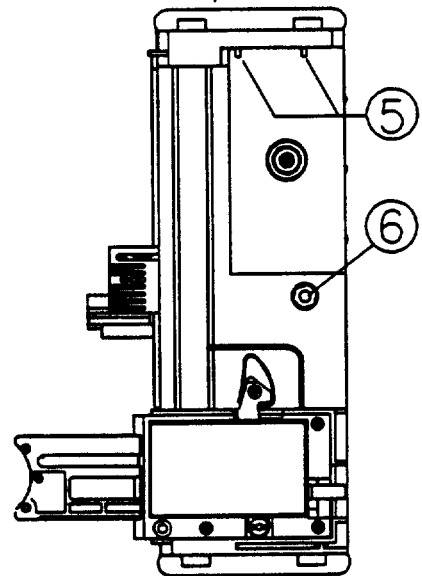
I.V. Pole Clamp

The pump is supplied with a detachable, adjustable clamp which allows the AS40A to be mounted to a standard vertical IV pole. The Pole Clamp can be adjusted to allow the pump to be used on a horizontal pole.



To attach the IV pole clamp to the AS40A, first slide the clamp in place, so that the MOUNTING PIN CUTOUTS (1) on the clamp engage the MOUNTING PINS (5) built into the rear of the pump. Tighten the MOUNTING SCREW (4) into the threaded RECESS (6) just below the battery cover. Tools are not required for this operation.

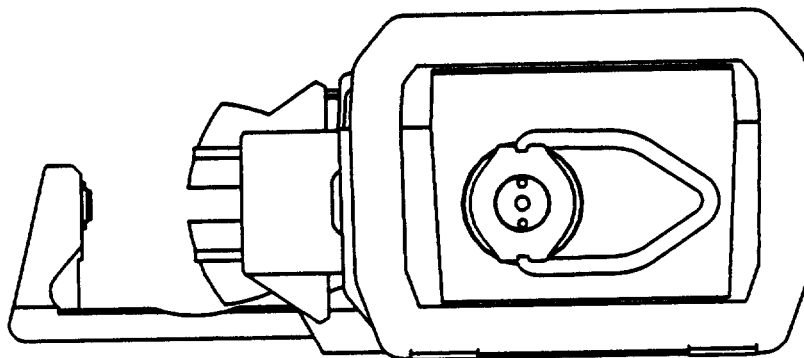
The JAW (3) clamps the pump to the IV pole. Turn the KNOB (2) counterclockwise to open the jaw, and clockwise to close it. Tighten the knob by hand only. Do not use tools to tighten the knob.



91

IV Pole Loop

The AS40A pump includes a IV pole loop built into the top of the pump. This loop may be swiveled as required, or folded down and out of the way when not in use.



Handwritten signature or initials.

Pump Maintenance

The standard AS40A requires minimal maintenance. However, the pump should be inspected daily for proper operation, as explained below. Spills and dirt should be cleaned off the pump as quickly as possible.

If the pump is used in a critical care situation, it should be monitored for frequent **[ATTACH CHARGER]** or **[BAD BATTERY]** messages, which may signify a need to replace the battery or to modify the user's recharging practices. As with all rechargeable batteries, the battery service life will vary according to usage. Overcharge and extreme temperatures will reduce battery service life.

Cleaning

All the external moving parts must be kept clean. Dirt, sticky films, or foreign substances that are allowed to harden may cause unnecessary delivery problems.

Do not sterilize by autoclave, ETO, gamma ray, or any other method that is harmful to plastic materials or electronic devices.

The exterior may be cleaned by a mist spray, or by wiping with a damp sponge, nonmetallic brush, swabs, etc. Blot dry with a soft cloth.

The moving parts may be cleaned by irrigation with a gentle water spray. Be sure the pump is held in a horizontal position, so the liquid drains out the side of the drive housing and not at the ends.

The charger plug and ON/OFF switch areas must be kept clean and dry at all times. Liquids spilled into the barrel clamp area may temporarily cause excess **[CHECK SYRINGE]** alerts. Drying generally restores proper operation.

Acceptable cleaning agents are:

- Mild, unscented detergent and water.
- Distilled or deionized water followed by hygroscopic (drying) rinse to promote drying.
- Dilute isopropyl alcohol (maximum concentration: 15%)
- Dilute ethyl alcohol
- Commercial nonabrasive germicidal cleansers, such as:
 - "kleenaseptic®" (Vickers)
 - "O-Syl®" (National Laboratories)



- "Zeptisol[®]" solution (Calgon Vestal Labs)
- "Staphene[®]" aerosol (Calgon Vestal Labs)
- "Bafix[®]" aerosol (Hysan Corp.)
- "Dow Cleaner[®]" (Dow Chemical)
- "Steriphene II[®]" (Spartan Chemical)
- "Amphyl[®]" (National Laboratories)
- "Omega[®]" and "A3" (Airwick Industries)
- 5% chlorine bleach solution in water

Follow manufacturer's dilution instructions for concentrated cleaners.

Do not use petroleum based spray solvents, penetrant, or any type of penetrating oil.

Daily Check

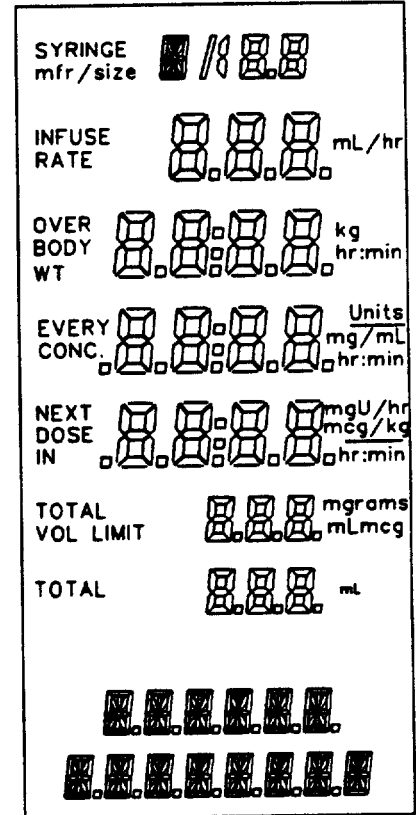
The Daily Check should be performed prior to programming an infusion.

Keypad Check

- 1) After the pump completes the power-up Lamp Test, press every key except the <▲> and <▼> arrow keys in any order, one key at a time. Each keypress should result in a short beep.
- 2) Press any two (or more) keys simultaneously. There should be no response.
- 3) Press and hold any key (except <▲>, <▼>, <START>, <STOP>). There should be only one beep, no matter how long the key is held down.
- 4) Press and hold any key (except <▲>, <▼>, <START>, <STOP>), then press any other key. There should be no response to the second keypress.
- 5) Press and briefly hold down the <START> and <STOP> keys, one at a time. The pump should sound repeated beeps while each key is held down. *Holding down the <START> key for a prolonged period of time may cause a "stuck key" failsafe alarm.*

Mechanical Check

- 1) Before using the pump, check for slippage of the plunger driver by applying gentle back pressure. If there is any sign of slippage, take the pump out of service. Check the plunger driver for free travel through its full range. Check the barrel clamp for free travel and proper locking.
- 2) When connecting the charger, make sure that the charger plug and socket are clean and fully engaged, and that the "ON CHARGE" light is on when the charger is plugged in.
- 3) Make sure the pad is in place on the barrel clamp. The pad is white rubber with a black plastic "pill" about 1/3 of the way from one end.



Display Check

- 1) Press and hold the <STOP> key during the normal power-up Lamp Test. This will show the entire display. Compare the display to the illustration. Verify that all annunciators, decimal points, and digits are legible.
- 2) Be sure that all lights on the Status Panel light up during the Lamp Test. Note: If the charger is plugged in, the **ON CHARGE** light will be on before, during, and after the Lamp Test.

In Case of Difficulty

Check the infusion set carefully to be sure the tubing is not pinched, and that there are no obstructions to prevent proper fluid flow.

Problems associated with a particular syringe size or manufacturer are likely to be caused by variations in syringe dimensions. Typical symptoms are: an inability to completely empty certain syringes, **[LINE OCCLUDED]** alarms when the syringe becomes empty, and frequent **[CHECK SYRINGE]** messages.

Avoid applying tape, paper stickers, labels, etc. to the syringe. Such materials increase the apparent diameter of the syringe barrel, which can impair the accuracy of the Syringe Recognition system.

Syringe Recognition problems may be caused by improperly mounted syringes. Excess clamping force can crush the syringe barrel, which results in an erroneous barrel diameter reading.

Syringe Detection problems (e.g. frequent **[CHECK SYRINGE]** messages) may be caused by improperly centering the syringe in the barrel clamp cradle.

If the pump fails to operate as described, contact Product Services for assistance:

(1-800-THE-PUMP, or 1-800-843-7867)

Alert and Alarm Displays

The AS40A notifies the user when important conditions occur:

- 1) **Error Responses:**
The wrong key has been pressed, or there is some other minor problem. An advisory message may accompany an error response.
- 2) **Alerts:**
A condition has occurred which requires attention.
- 3) **Alarms:**
Immediate action is required in order to proceed with operation.
- 4) **Failsafe Alarms:**
Something is wrong, and the pump has gone into a "failsafe shutdown" condition.

The red ALERT light flashes during an alert or an alarm, to indicate that operator attention is necessary. The front panel and status lights may display additional information.

Some messages may fit more than one category, depending on circumstances. To avoid confusion, the alert/alarm descriptions are grouped as shown below:

Error Responses	Alerts
<div> <div>[▼▲ IN USE]</div> <div>[DATA MISSING]</div> <div>[KEYPAD LOCKED]</div> <div>[NOT ALLOWED]</div> <div>[PUMP LIMIT]</div> <div>[SIZE UNKNOWN]</div> </div> <div> <div>[CHECK SYRINGE]</div> <div>[FINISH EDITING]</div> <div>[LOAD SYRINGE]</div> <div>[OUT OF RANGE]</div> <div>[SIZE MISMATCH]</div> </div>	<div> <div>[<10 MIN EMPTY]</div> <div>[<10 MIN(drug name)]</div> <div>[BOLUS > (drug max)]</div> <div>[DOSE > (drug max)]</div> <div>[EDITING]</div> <div>[RATE > (drug max)]</div> <div>[SILENT RUNNING]</div> <div>[VERIFY < (drug min)]</div> </div> <div> <div>[<10 MIN VOL LIM]</div> <div>[ATTACH CHARGER]</div> <div>[BOLUS < (drug min)]</div> <div>[DOSE < (drug min)]</div> <div>[PUMP IS IDLE]</div> <div>[RATE < (drug min)]</div> <div>[VERIFY > (drug max)]</div> </div>
Failsafe Alarms	Alarms
<div> <div>[BAD BATTERY]</div> <div>[POWER FAULT]</div> <div>[(error code)]</div> </div>	<div> <div>[CAL SENSORS]</div> <div>[DOSE DUE]</div> <div>[DRUGS CORRUPT]</div> <div>[EMPTY]</div> <div>[VOLUME LIMIT]</div> </div> <div> <div>[DOSE COMPLETE]</div> <div>[DRUG CORRUPT]</div> <div>[DRUGS INVALID]</div> <div>[LINE OCCLUDED]</div> </div>

Error Responses

An inappropriate keypress is signaled by a short beep. Most problems or programming errors are signaled by an audible tone and an error message.

MESSAGE: [▼▲ IN USE] (1 beep)

CAUSE: Trying to use digit keys to edit a number that has been modified with an arrow key. Numbers can be entered with digit keys or with arrow keys, but not both at the same time.

CORRECTION: Continue programming with the arrow keys, or clear the field and reprogram it with digit keys.

MESSAGE: [CHECK SYRINGE] (single or continuous short beeps)

CAUSE: The syringe is improperly mounted.

CORRECTION: Any key silences the audible tone. Make sure the syringe is centered in the barrel clamp cradle, and that the syringe flange (tab) is in the barrel clamp tab slot. Use the heel of the hand to press the barrel clamp firmly against the syringe.

If this alarm occurs during an infusion, then after correcting the problem, press <START> to resume the infusion.

MESSAGE: [DATA MISSING] (1 beep)

CAUSE: Pressing <START>, <PURG>, or <BOLUS> when the program information is incomplete.

CORRECTION: Enter the additional data required. See "Purge Operation" and "Bolus Operation" sections.

MESSAGE: [FINISH EDITING] (1 beep)

CAUSE: Pressing <START> while a field is open for editing.

CORRECTION: Complete the editing process.

MESSAGE: [KEYPAD LOCKED] (1 beep)

CAUSE: Pressing a key while the LOCK function is active.

CORRECTION: Press <LOCK> to unlock the keypad.

MESSAGE: [LOAD SYRINGE] (1 beep)

CAUSE: Attempt to start an infusion without a syringe in place.

CORRECTION: Mount a syringe after manually purging.

MESSAGE: [NOT ALLOWED] (1 beep)

CAUSE: <BOLUS> key pressed when the bolus feature is not allowed for the selected drug.

CORRECTION: Use drug selection [GENERAL].

MESSAGE: [OUT OF RANGE] (1 beep)

CAUSE: No bolus is possible for the current combination of syringe, body weight, and drug concentration.

CORRECTION: Use a different syringe or drug concentration.

MESSAGE: [PUMP LIMIT] (1 beep)

CAUSE: Attempt to program a value outside the pump's acceptable range.

CORRECTION: Pump displays nearest acceptable value. Press <CONFIRM> to accept displayed value, or else enter a different value and press <CONFIRM>.



MESSAGE: [SIZE MISMATCH] (single beep)

CAUSE: The detected syringe size is different from the programmed size.

CORRECTION: Press <CLR> as required. The pump will prompt for verification of syringe manufacturer, and then will check the syringe size again.

MESSAGE: [SIZE UNKNOWN] (single beep)

CAUSE: The pump cannot identify the syringe size for the selected manufacturer.

CORRECTION: Check to be sure the correct manufacturer has been programmed. Ensure that the barrel clamp is fully closed.

Alerts

MESSAGE: [<10 MIN EMPTY] (15 beeps)

CAUSE: At the present rate of infusion, approximately 10 minutes remain until the syringe is empty.

Note: Since this function is sensitive to variations in syringe dimensions, the exact timing of this alarm may vary.

CORRECTION: Any key silences the audible tone. The alarm is reset when a filled syringe is installed, or when the plunger driver is moved back.

MESSAGE: [<10 MIN (drug name)] (15 beeps)

CAUSE: At the present rate of infusion, approximately 10 minutes remain until either the volume limit setting is reached, or the syringe is empty.

CORRECTION: Any key silences the audible tone.

MESSAGE: [<10 MIN VOL LIM] (15 beeps)

CAUSE: At the present rate of infusion, approximately 10 minutes remain until the volume limit setting is reached.

CORRECTION: Any key silences the audible tone.

MESSAGE: [ATTACH CHARGER] (10 long beeps, flashing BATTERY light)

CAUSE: The internal battery needs charging. If a charger is not connected, or is not charging the battery, this alarm will repeat every 15 minutes.

CORRECTION: Connect the charger. When the battery charge reaches the normal operating range, the alarm will self-cancel.

Note: If the battery voltage is very low, the alarm may recur once or twice after the charger is connected.

**MESSAGE: [VERIFY > (drug max)] or [VERIFY < (drug min)]
[BOLUS > (drug max)] or [BOLUS < (drug min)]
[DOSE > (drug max)] or [DOSE < (drug min)]
[RATE > (drug max)] or [RATE < (drug min)]**

CAUSE: User attempted to enter a program value outside the normal range for a selected drug.

These are precautionary messages, calling attention to the fact that unusual infusion parameters have been entered. The [VERIFY ...] message appears the first time the field is programmed with an extra large or small value. If the same field is later edited with a different value that is still outside the normal range, the message will be [DOSE ...], [RATE ...], or [BOLUS ...] (whichever is applicable) instead.

MESSAGE: [EDITING] (no audio, or continuous beeps)

CAUSE: The [EDITING] message appears while a data entry field is being edited. The continuous beeps occur when:

- 1) An infusion is in progress,
- 2) The Rate or Dose field is being edited, and

201

- 3) There has been no keypress for 15 seconds.

CORRECTION: Complete the editing operation.

MESSAGE: [PUMP IS IDLE] (15 beeps, or continuous beeps)

CAUSE: The pump has been in Standby state for at least 2 minutes. Also occurs if there is no keypress within 15 seconds after the infusion is stopped.

CORRECTION: Any key silences the audible tone. The Lock function suppresses this alert. Note: If the keypad is locked, there will be no beeps, but the [PUMP IS IDLE] message will still appear.

MESSAGE: [SILENT RUNNING] (Single Dose mode only)

CAUSE: The pump is configured to enable "Silent Running" operation and the pump is infusing in Single Dose mode.

CORRECTION: This is an informational display. If Silent Running is not desired, the pump must be reconfigured to disable this feature.

Alarms

MESSAGE: [DOSE COMPLETE] (continuous beeps)

CAUSE: ("Single Dose" infusion only) The programmed dose has been delivered.

CORRECTION: Any key silences the audible tone.

MESSAGE: [DOSE DUE] (continuous beeps)

CAUSE: ("Manual Schedule" infusion only) The NEXT DOSE IN timer has reached [0:00], and the next dose is due to be delivered.

CORRECTION: Any key silences the audible tone. Press **<START>** to deliver the scheduled dose.

MESSAGE: **[DRUG CORRUPT]**, **[DRUGS CORRUPT]**, **[DRUGS INVALID]** (single beep)

CAUSE: The pump has detected an error in the internally stored drug library information.

CORRECTION: Repair is advised. Remove the pump from service as soon as possible. The **[DRUGS CORRUPT]** and **[DRUGS INVALID]** errors automatically disable the Drug Library. The **[DRUG CORRUPT]** error disables the affected drug, but allows selecting from the remaining drugs.

MESSAGE: **[EMPTY]** or **[EMPTY (drug name)]** (continuous beeps)

CAUSE: The syringe is empty.

CORRECTION: Any key silences the audible tone. Release and slide the plunger driver back at least 1½ inch (4 cm) to reset the alarm. Note: due to variability in syringe dimensions, some syringes may cause a **[LINE OCCLUDED]** alarm to occur before the **[EMPTY]** alarm.

MESSAGE: **[LINE OCCLUDED]** (flashing ALERT light, continuous beeps)

CAUSE: There is a line constriction or other condition that causes excess plunger force.

CORRECTION: The alarm automatically stops the pump. Any key silences the audible tone. Check for empty syringe, kinked tubing, clogged catheter, etc. Check for foreign material preventing movement of the pump mechanism. **RELIEVE RESIDUAL SYRINGE PRESSURE BY RELEASING THE PLUNGER DRIVER.** An unintentional small bolus may occur when the blockage is cleared, if the plunger driver is not released. The message clears when the infusion is successfully restarted.

MESSAGE: [VOLUME LIMIT] (flashing ALERT light, continuous beeps)

CAUSE: The programmed volume limit has been reached.

CORRECTION: Any key silences the audible tone. Restarting the pump (by pressing <START> or initiating a bolus) will reset the Volume Limit field.

Failsafe Alarms

Failsafe alarms only occur when proper operation cannot be assured. The infusion cannot be restarted, and must be reprogrammed after the problem has been corrected. The pump must be turned off to clear the alarm.

MESSAGE: [BAD BATTERY] (SYSTEM and BATTERY lights illuminated. Continuous, alternating High/Low long beeps.)

CAUSE: The battery voltage is below minimum operating level.

CORRECTION: Connect the charger and recharge the battery for at least 16 hours.

MESSAGE: [POWER FAULT] (SYSTEM and BATTERY lights illuminated. Continuous, alternating High/Low long beeps)

CAUSE: The pump's internal power supply is out of tolerance.

CORRECTION: Repair is required. Remove the pump and charger from service.

MESSAGE: [(error code)] (SYSTEM light illuminated, alternating High/Low long beeps)

CAUSE: An internal error has been detected.

CORRECTION: Repair is required. Note all displayed error codes. Make a note of the conditions prior to the error. Take the pump out of service.

Note: In some cases, there may not be a legible error code display.

Warranty

Baxter Healthcare Corporation ("Baxter") warrants that the equipment shall be free from defects in material and workmanship when delivered to the original purchaser. Baxter's sole obligation shall be limited to repair or replacement at Baxter's option and expense, of the defective part or unit for a period of one year following the date of initial delivery.

The warranty extends only to the original purchaser and is not assignable or transferable, and shall not apply to auxiliary equipment or disposable accessories.

THERE ARE NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY AND ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHICH EXTEND BEYOND THE DESCRIPTION OF THE PRODUCT AND THOSE EXPRESSLY SET FORTH IN ITS LABELING. UNLESS USED ACCORDING TO THE DIRECTIONS ACCOMPANYING THE PRODUCT, ALL WARRANTIES ARE SPECIFICALLY EXCLUDED. In no event shall Baxter Healthcare Corporation be responsible for incidental, consequential, or exemplary damages. Modification, alteration, recalibration or abuse, and service by other than a Baxter Healthcare Corporation authorized representative may void the warranty.

Service Information

While under Baxter Healthcare Corporation Warranty, Service Agreement (optional), or lease agreement, the instrument must not be opened by unauthorized personnel.

To contact Baxter Healthcare Corporation Customer Service Division for service and repair information for all instruments, call 1-800-THE-PUMP or 1-800-843-7867.

Shipping costs for all units returned to Baxter Healthcare Corporation shall be paid by the customer. The unit must be packed in its original container or in another Baxter approved container that will provide adequate protection during shipment. To ensure prompt return, a Baxter Product Service representative must be notified before shipping any unit for repair. When calling Baxter Product Service, please be prepared to provide code number and serial number of the unit. A service request number will be issued and should accompany all communications. A brief written description of the problem should be attached to the instrument when it is returned for service.

Baxter Healthcare Corporation will not be responsible for unauthorized returns or for units damaged in shipment due to improper packing.



INDEX

- " ... " (quotes) 1
- "Auto Schedule" 11, 22, 35, 50
- "Fixed" 31, 37-39, 55
- "Manual Schedule" 11, 21, 22, 33, 34, 50, 68
- "mcg/kg/min" 10, 22, 37, 38, 50, 51
- "mcg/min" 10, 22, 36, 37, 50
- "mL/hr" 1, 10, 20, 21, 28-30, 36, 50, 53
- "Single Dose" 11, 21, 31, 32, 50, 68
- "Units/hr" 10, 20, 21, 50
- "Variable" 10, 55
- "Variable" concentration 55
- Accuracy 13, 62
- ALERT light 17, 34, 63, 69, 70
- Angle Brackets 1
- Annunciators 14, 19, 38, 40, 48, 61
- Audio range 50-52, 55
- Auto Lock 2, 34, 48, 50, 51, 53, 55
- Barrel Clamp 8, 9, 26, 52, 59, 61, 62, 64, 66
- Battery Charger 2, 3, 13, 17, 56
- BATTERY Light 17, 67
- Bolus 2, 4, 7, 10, 15-18, 20, 24, 25, 29-32, 34-39, 44-46, 64, 65, 69, 70
- Cleaning 59
- Configuration 2, 3, 5, 20, 48-55
- Configuration Review 49, 50, 54
- Continuous Infusion 10, 21, 22, 30
- Cradle 8, 9, 26, 62, 64
- Custom Configuration 54
- Daily Check 5, 19, 27, 60
- Data test 19, 41
- Defaults 51, 55
- Deliverable Volume 13, 44
- Deliverable Volumes 24
- Delivery Mode 7, 28, 32, 34, 39
- Delivery Modes 28, 48
- Delivery Rate 32, 35, 36, 38, 53
- Delivery Rates 30
- Digit Keys 16, 29, 39, 45, 64
- Dose Duration 11, 15, 31, 33
- Dose Interval 11, 15
- Dose Size 11, 15
- Driver 4, 8, 9, 25, 26, 42, 61, 66, 69
- Drug Concentration 10, 15, 20, 21, 22, 30, 36-40, 44, 45, 65
- Drug Default 50, 55
- Drug Library 1-3, 7, 9-11, 13, 20, 27, 28, 30, 31, 33, 35-40, 50, 51, 55, 69
- Drugs 4, 6, 20, 31, 50, 55, 69
- Editing 34, 39-41, 46, 47, 64, 68
- Epidural 2, 6
- Epidural Administration 6
- Error 19, 40, 52, 63, 64, 69, 70
- Failsafe 17, 60, 63, 70
- Finger Grip 8, 25, 26
- Fixed 20, 31, 32, 37-39, 42-44, 50, 55
- Fixed concentration 50
- Identifier 27, 54, 55
- Idle Alarm 34, 50, 51, 53, 55
- Infusion Mode 20, 30, 33, 44
- Infusion Modes 2, 10, 11, 20, 21, 28, 50, 51

Infusion Set 25, 62
 Interval 11, 15, 21, 22, 33
 Keypad 1-3, 8, 13, 16, 17, 60,
 65, 68
 Lamp Test 5, 27, 54, 60, 61
 LCD 8, 13, 14, 27, 39, 41, 45
 Lock 2, 16, 17, 29-31, 34, 36,
 37, 48, 50, 51, 53,
 55, 65, 68
 LOCK light 17, 48
 Maintenance 59
 Messages 2, 15, 40, 59, 62, 63,
 67
 Miscellaneous 51, 54
 Mivacurium 51
 Mode 4, 5, 7, 10, 11, 14, 20, 21,
 22, 27-40, 44, 49,
 50, 51, 53, 55, 68
 Mode Default 50, 55
 Number Keys 7
 Occlusion Sensitivity 51, 52
 ON CHARGE light 17, 61
 Operating States 18
 Plunger Clamp 8, 27
 Plunger Driver 4, 9, 42, 61, 66,
 69
 Pole Clamp 2, 8, 57
 Power 4, 13, 60, 61, 70
 Prime 25
 Problems 59, 62, 64
 PSI Range 50-52, 55
 Purge 4, 9-11, 16-18, 25, 42, 43,
 48, 64
 Quotes 1
 Rate Range 13, 23, 43, 50, 51,
 53, 55
 RUN lights 17, 18, 34

Run State 17, 18, 40
 Silent Running 5, 31, 50, 51, 53,
 55, 68
 Size Override 5, 50-52, 55
 Square Brackets 1
 STANDBY light 17, 18, 34
 Standby State 4, 17, 18, 34, 35,
 39, 42, 44, 45, 47,
 68
 Status lights 17, 63
 Syringe Data 23, 25, 29, 30, 44,
 45
 Syringe Detection 26, 51, 52,
 55, 62
 Syringe Manufacturer 2, 5, 7,
 15, 29-31, 33, 36,
 37, 47, 52, 66
 Syringe Manufacturers 29, 51
 Syringe Recognition 5, 47, 51,
 52, 55, 62
 Syringes 2, 13, 62, 69
 SYSTEM light 17, 70
 Temperature 13, 56
 Terminating 54
 Timed Infusion 11, 33
 Timed Infusions 21
 Total Delivered 15, 35, 43, 46,
 48
 Variable 10, 14, 20, 50, 55
 Variable Concentration 50
 Volume Limit 10, 15, 24, 29, 40,
 50, 51, 53, 55, 66,
 67, 70
 [...] (square brackets) 1

TEXT MESSAGES

[<10 MIN (drug name)] 53, 66
 [<10 MIN EMPTY] 5, 31, 53, 63, 66
 [<10 MIN VOL LIM] 63, 67
 [ATTACH CHARGER] 59, 63, 67
 [AUDIO RANGE] 52
 [AUTO LOCK] 53
 [BAD BATTERY] 59, 63, 70
 [BOLUS < (drug min)] 44, 63, 67
 [BOLUS > (drug max)] 44, 63, 67
 [BOLUS READY] 45
 [CAL SENSORS] 63
 [CHECK SYRINGE] 26, 59, 62, 63, 64
 [DATA MISSING] 45, 63, 64
 [DOSE < (drug min)] 63, 67
 [DOSE > (drug max)] 63, 67
 [DOSE CANCELED] 32
 [DOSE COMPLETE] 5, 31, 53, 63, 68
 [DOSE DUE] 33, 34, 63, 68
 [DOSE RESUMES] 32, 46
 [DRUG CORRUPT] 63, 69
 [DRUG LIBRARY] 51
 [DRUGS CORRUPT] 63, 69
 [DRUGS INVALID] 63, 69
 [EDITING] 63, 67
 [EMPTY (drug name)] 69
 [EMPTY] 63, 69
 [FINISH EDITING] 63, 64
 [GENERAL] 10, 11, 20, 28, 30, 31, 33, 35-37, 50, 55, 65
 [IDLE ALARM] 53
 [KEYPAD LOCKED] 63, 65
 [LINE OCCLUDED] 4, 62, 63, 69

[LOAD SYRINGE] 63, 65
 [NOT ALLOWED] 63, 65
 [OUT OF RANGE] 63, 65
 [POWER FAULT] 63, 70
 [PRESS EDIT TO SET BOLUS SIZE] 45
 [PSI RANGE] 52
 [PUMP IS IDLE] 53, 63, 68
 [PUMP LIMIT] 19, 40, 63, 65
 [RATE < (drug min)] 63, 67
 [RATE > (drug max)] 63, 67
 [RATE RANGE] 53
 [SELECT DRUG ▼▲] 7, 27, 28, 49
 [SELECT MODE ▼▲] 7, 20, 27, 28, 29-31, 33, 35, 36, 37, 49
 [SILENT RUNNING] 53, 63, 68
 [SIZE MISMATCH] 63, 66
 [SIZE OVERRIDE] 52
 [SIZE UNKNOWN] 63, 66
 [SYRINGE DETECT] 52
 [SYRINGE RECOGNIT] 52
 [VERIFY < (drug min)] 63, 67
 [VERIFY > (drug max)] 63, 67
 [VIEW DFAULTS?] 50, 51
 [VIEW DRUGS?] 50
 [VIEW MFRS?] 49-51
 [VIEW MISC?] 50, 51
 [VIEW MODES?] 49, 50
 [VOLUME LIMIT] 53, 63, 70
 [▼▲ IN USE] 63, 64

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JAN 7 1994

149

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BAXTER AS40A INFUSION PUMP-STANDARD DRUG LIBRARY **for devices with Serial Numbers ending in "D2"**

The AS40A Drug Library is a configuration option developed to facilitate pump infusion setup for individual patients based upon input from clinical users. Refer to the Operation Manual for Drug Library usage instructions and the Technical/Service Manual for Drug Library Configuration procedures. Before using the library for any specific drug, refer to the full prescribing information supplied by the drug manufacturer.

DRUG	PUMP DRUG NAME	CONC. ¹ mg/mL	DOSE INFUSION RATE			BOLUS ²	BOLUS SIZE			
			LOW	DEFAULT	HIGH		LOW	DEFAULT	HIGH	UNITS
Alfentanil	ALFENTAN	0.25	0.5	1.5	3.	50.	25.	75.	175.	mcg/kg
Alfentanil	ALFENTAN	0.5	0.5	1.5	3.	50.	25.	75.	175.	mcg/kg
Amrinone	AMRINONE	5.	5.	7.5	10.	250.	100.	500.	2000.	mcg/kg
Atracurium	ATRACURI	2.	2.	7.	15.	400.	150.	300.	550.	mcg/kg
Atracurium	ATRACURI	10.	2.	7.	15.	400.	150.	300.	550.	mcg/kg
Dobutamine	DOBUTAMI	1.	2.	3.	15.					
Dobutamine	DOBUTAMI	5.	2.	3.	15.					
Dobutamine	DOBUTAMI	5.	50.	200.	1000.					
Dopamine	DOPAMINE	0.8	1.	3.	20.					
Dopamine	DOPAMINE	4.	1.	3.	20.					
Dopamine	DOPAMINE	4.	50.	200.	1000.					
Dopamine	DOPAMINE	8.	50.	200.	1000.					
Epinephrine	EPINEPHR	0.01	0.005	0.1	0.2					
Epinephrine	EPINEPHR	0.02	0.005	0.1	0.2					
Epinephrine	EPINEPHR	0.02	0.1	1.	8.					
Esmolol	ESMOLOL	50.	50.	100.	200.	500.	125.	250.	1000.	mcg/kg
Fentanyl	FENTANYL	0.025	0.02	0.05	0.2	2.5	1.	5.	50.	mcg/kg
Fentanyl	FENTANYL	0.05	0.02	0.05	0.2	2.5	1.	5.	50.	mcg/kg
Fentanyl	FENTANYL	0.05	0.2	0.5	2.					
General	GENERAL									

¹Concentration for Heparin and Insulin are in Units/mL.

²The bolus rate is the lesser of: the maximum rate of the selected syringe size or the bolus rate in the above chart.

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BAXTER AS40A INFUSION PUMP-STANDARD DRUG LIBRARY
for devices with Serial Numbers ending in "D2"

The AS040A Drug Library is a configuration option developed to facilitate pump infusion setup for individual patients based upon input from clinical users. Refer to the Operation Manual for Drug Library usage instructions and the Technical/Service Manual for Drug Library Configuration procedures. Before using the library for any specific drug, refer to the full prescribing information supplied by the drug manufacturer.

DRUG	PUMP DRUG NAME	CONC. ¹ mg/mL	DOSE INFUSION RATE			UNITS	BOLUS SIZE			UNITS
			LOW	DEFAULT	HIGH		LOW	DEFAULT	HIGH	
Heparin	HEPARIN ¹	200.	300.	1000.	1600.	Units/hr				
Insulin	INSULIN ¹	1.	1.	4.	20.	Units/hr				
Isoproterenol	ISOPROTE	0.01	0.01	0.025	0.1	mcg/kg/min				
Isoproterenol	ISOPROTE	0.02	0.01	0.025	0.1	mcg/kg/min				
Isoproterenol	ISOPROTE	0.02	0.1	1.	5.	mcg/min				
Lidocaine	LIDOCAIN	40.	500.	1000.	4000.	mcg/min	30.	70.	110.	mg
Mivacurium	MIVACURI	0.5	4.	8.	15.	mcg/kg/min	100.	150.	350.	mcg/kg
Mivacurium	MIVACURI	2.	4.	8.	15.	mcg/kg/min	100.	150.	350.	mcg/kg
Nitroglycerine	NITROGLY	1.	0.5	1.	5.	mcg/kg/min				
Nitroglycerine	NITROGLY	1.	10.	30.	1000.	mcg/min				
Nitroprusside	NITROPRU	0.2	0.01	0.1	3.	mcg/kg/min				
Norepinephrine	NOREPINE	0.02	0.25	1.	10.	mcg/min				
Prostaglandin	PGE1	0.005	0.025	0.05	0.2	mcg/kg/min				
Phenylephrine	PHENYLEP	0.2	3.	10.	30.	mcg/min				
Procainamide	PROCAINA	40.	500.	1000.	4000.	mcg/min	100.	250.	600.	mg
Propofol	PROPOFOL	10.	25.	100.	200.	mcg/kg/min	200.	1000.	2500.	mcg/kg
Sufentanil	SUFENTAN	0.005	0.01	0.025	0.1	mcg/kg/min	0.1	1.	5.	mcg/kg
Sufentanil	SUFENTAN	0.05	0.01	0.025	0.1	mcg/kg/min	0.1	1.	5.	mcg/kg
Vecuronium	VECURONI	0.2	0.7	1.	1.3	mcg/kg/min	40.	75.	150.	mcg/kg
Vecuronium	VECURONI	1.	0.7	1.	1.3	mcg/kg/min	40.	75.	150.	mcg/kg

Concentration for Heparin and Insulin are in Units/mL.

²The bolus rate is the lesser of: the maximum rate of the selected syringe size or the bolus rate in the above chart.

151

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17

Baxter

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152
013

PROPOSED
LABELING

24

Proposed Labeling

Note: The proposed Operator's Manual differs from the current one only by one page. Only that page is included in this attachment.

Device Description

The AS40A Infusion Pump is designed to meet the fluid and drug delivery requirements of today's changing clinical environment. It provides for accurate continuous or intermittent infusion via intravenous (IV), intra-arterial (IA), epidural, or subcutaneous routes of administration.

The AS40A accepts standard disposable syringes from 1 mL to 60 mL in size. A numeric keypad simplifies programming and makes the pump easier to use. Safety and effectiveness are reinforced by pre-programmable bolus operation, titration of a dose without interruption of fluid flow, and easily understood alarm and alert messages.

The AS40A can be custom configured for the healthcare facility. This allows an institution or clinic to select those key features which meet specific requirements. Configurable options include: Drug Library feature, syringe manufacturer, automatic syringe size recognition, selectable infusion modes, maximum infusion rates, occlusion pressure sensitivity, and keypad auto lock. The selected options can be reviewed easily by the user and the chosen configuration can be changed to meet new or different requirements.

The AS40A can run on its internal rechargeable battery pack and can also be operated while attached to a battery charger.

The AS40A is supplied with a pole clamp and a built-in IV pole loop. The pump can also be used as a table-top unit.

→ This paragraph will be changed to read:

The AS40A Infusion Pump is designed to meet the fluid and drug delivery requirements of today's changing clinical environment. It provides for accurate or intermittent infusion of intravenous solutions, drug solutions, or blood and packed red blood cells. The pump is indicated for infusion via the intravenous (IV), intra-arterial (IA), epidural, or subcutaneous routes of administration.

COMPARISON TABLE

207

Comparison of Features

Auto Syringe® AS40A Infusion Pump

vs.

Medfusion 2001 Infusion Pump

Comparison of Features
Auto Syringe® AS40A Infusion Pump vs. Medfusion 2001 Infusion Pump

Features	AS40A (without blood pumping indication)	AS40A (with blood pumping indication)	Medfusion 2001
Size (W x D x H)	3.5" x 2.5" x 10"	3.5" x 2.5" x 10"	4.5" x 3" x 7.5"
Weight	2.75 lbs.	2.75 lbs.	2.5 lbs
Battery life	12 hours at 2 ml/hr	12 hours at 2 ml/hr	10 hours at 5 ml/hr
Flow rate range	0.01 to 360 ml/hr (Syringe dependent)	0.01 to 360 ml/hr (Syringe dependent)	.01 to 378 ml/hr (Syringe dependent)
Delivery modes	ml/hr, volume/time Automatic intermittent Manual intermittent mcg/kg/min, mcg/min, Units/hr	ml/hr, volume/time Automatic intermittent Manual intermittent mcg/kg/min, mcg/min, Units/hr	ml/hr, volume/time Automatic intermittent Manual intermittent
Syringes accepted	B-D 1 - 60 Monoject 1 - 60 Terumo 1 - 60	B-D 1 - 60 Monoject 1 - 60 Terumo 1 - 60	B-D 1 - 60 Monoject 1 - 60 Terumo 1 - 60
Occlusion pressure	Selectable Low, medium, high	Selectable Low, medium, high	Set
Indications for use	continuous or intermittent infusion of intravenous or drug solutions via intravenous, intra-arterial, epidural or sub-cutaneous routes of administration	continuous or intermittent infusion of intravenous or drug solutions via intravenous, intra-arterial, epidural or sub-cutaneous routes of administration; infusion of whole blood and packed red blood cells	Continuous or intermittent infusion of blood, lipids, fluids, antibiotics and other drugs requiring precisely controlled infusion rates
Custom programmable options	Volume limit, Syringe size, Syringe manufacturer, Alarm volume, Maximum rate, Security lock, PSI, Hospital location I.D., Delivery modes	Volume limit, Syringe size, Syringe manufacturer, Alarm volume, Maximum rate, Security lock, PSI, Hospital location I.D., Delivery modes	Volume limit, Syringe size, Syringe manufacturer, Alarm volume, KVO, Alarm delay time, Delivery modes
Bolus	Can deliver bolus before, during or after standard infusion	Can deliver bolus before, during or after standard infusion	No bolus capability
Purge/prime	Press purge and purge starts	Press purge and purge starts	Press hold the prime key for entire prime
RS 232	Yes	Yes	No

OPERATION MANUAL

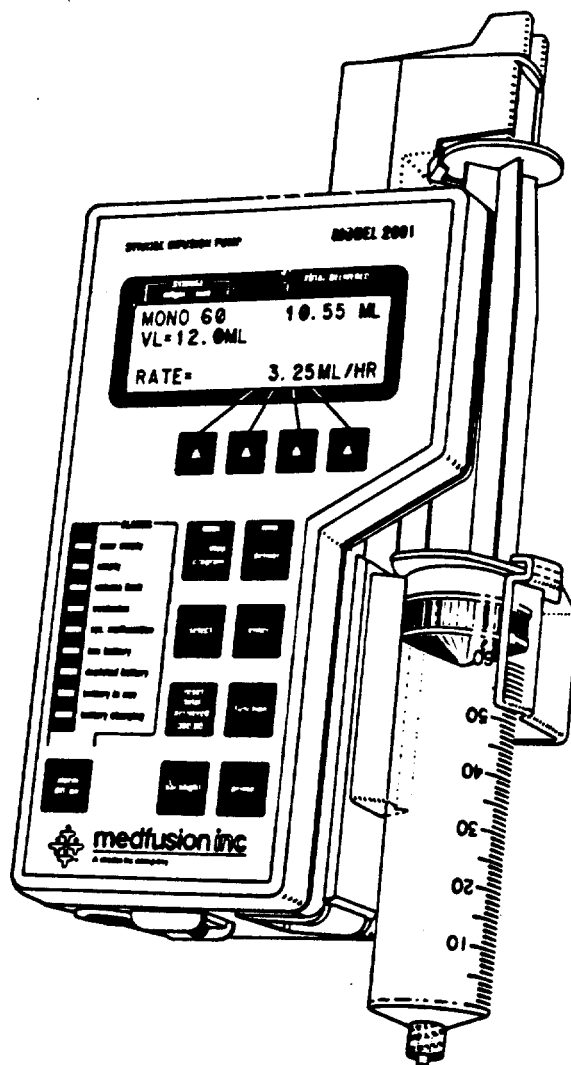
200

510(k) Premarket Notification
Blood Infusion Indication for
Auto Syringe® AS40A Infusion Pump
January 7, 1994

Medfusion Model 2001 Syringe Infusion Pump
Operations Manual

MODEL 2001

MEDFUSION SYRINGE INFUSION PUMP



OPERATIONS MANUAL

MEDFUSION, INC. 3450 River Green Court, Duluth, Georgia 30136 (USA) (404) 623-9809

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TABLE OF CONTENTS

	Page
Section I INTRODUCTION	1
Section II GENERAL SPECIFICATIONS	2
Section III GENERAL DESCRIPTION/DIAGRAM	4
Section IV CUSTOM PROGRAM MODE	5
Step 1: Entering the Custom Program (CP) Mode	5
Step 2: Preprogramming Delivery Modes	6
Step 3: Programming Maximum Rate (Only If Continuous Mode Was Selected)	8
Step 4: Programming Options	9
Table I: Programming Options	10
Section V OPERATING INSTRUCTIONS	11
Step 1: Syringe Loading	11
Step 2: Turning the Pump "On"; Reviewing the Custom Programmed Features and Pump Self Test	14
Step 3: Programming - Introduction	16
Section VI USER MODES	19
<u>Continuous Infusion</u>	
Step 1: Continuous Infusion	19
Step 2: Programming Syringe Manufacturer (Custom Programmable)	19
Step 3: Programming Syringe Size	20
Step 4A: Programming the Volume Limit (Custom Programmable)	21
Step 4B: Programming No Volume Limit	21
Step 5A: Programming KVO (Keep Vein Open) Rate (Custom Programmable)	22
Step 5B: Programming No KVO Rate	22
Step 6: Programming Rate	23
Step 7: Priming	24
Step 8A: Delivery	25
Step 8B: Running Volume (Only If VL Is Programmed)	25
Step 9A: Stop Delivery	26
Step 9B: End of Delivery - Volume Limit Without KVO	26
Step 9C: End of Delivery - Volume Limit With KVO	26
Step 10: Programming Standby Time	26

203

<u>Volume/Time</u>	27
Step 1: Volume/Time	27
Step 2: Programming Syringe Manufacturer	28
Step 3: Programming Syringe Size	
Step 4: Programming the Volume Limit (Custom Programmable)	29
Step 5A: Programming KVO (Keep Vein Open) Rate (Custom Programmable)	29
Step 5B: Programming No KVO Rate	30
Step 6: Programming Dose Volume (DV)	30
Step 7: Programming Delivery Time (DT)	31
Step 8: Priming	32
Step 9A: Delivery	
Step 9B: Running Volume (Only If VL Is Programmed)	32
Step 10A: Stop Delivery	33
Step 10B: End of Delivery Without KVO	33
Step 10C: End of Delivery With KVO	33
Step 11: Programming Standby Time	
<u>Intermittent Automatic</u>	34
Step 1: Intermittent Automatic	34
Step 2: Programming Syringe Manufacturer	35
Step 3: Programming Syringe Size	
Step 4A: Programming the Volume Limit (Custom Programmable)	36
Step 4B: Programming No Volume Limit	36
Step 5A: Programming KVO (Keep Vein Open) Rate (Custom Programmable)	37
Step 5B: Programming No KVO Rate	37
Step 6: Programming Dose Volume (DV)	38
Step 7: Programming Delivery Time (DT)	38
Step 8: Programming the Time Between Deliveries (TB)	39
Step 9: Priming	40
Step 10A: Delivery	
Step 10B: Running Volume (Only If VL Is Programmed)	41
Step 11A: Standby With KVO	42
Step 11B: Standby Without KVO	42
Step 11C: Automatic Delivery Begins	42
Step 12A: Stop Delivery	
Step 12B: End of Delivery -- Volume Limit (VL) Without KVO	43
Step 12C: End of Delivery -- Volume Limit With KVO	43
Step 13: Reset Standby Timer	44

224

	<u>Intermittent Manual</u>	45
	Step 1: Intermittent Manual	45
	Step 2: Programming Syringe Manufacturer	46
	Step 3: Programming Syringe Size	47
	Step 4A: Programming the Volume Limit (Custom Programmable)	47
	Step 4B: Programming No Volume Limit	48
	Step 5A: Programming KVO (Keep Vein Open) Rate (Custom Programmable)	48
	Step 5B: Programming No KVO Rate	49
	Step 6: Programming Dose Volume (DV)	49
	Step 7: Programming Delivery Time (DT)	50
	Step 8: Programming the Time Between Deliveries (TB)	50
	Step 9: Priming	51
	Step 10A: Delivery	52
	Step 10B: Running Volume (Only If VL Is Programmed)	52
	Step 11A: Standby With KVO	53
	Step 11B: Standby Without KVO	53
	Step 11C: Next Delivery Alert	53
	Step 12A: Stop Delivery	54
	Step 12B: End of Delivery -- Volume Limit Without KVO	54
	Step 12C: End of Delivery -- Volume Limit With KVO	54
	Step 13: Reset Standby Timer	56
SECTION VII	OTHER KEY FUNCTIONS	58
SECTION VIII	ALARMS/ALERTS	61
SECTION IX	BATTERY POWER	63
SECTION X	BATTERY VOLTAGE	64
SECTION XI	IV POLE OR RAIL ATTACHMENT	65
SECTION XII	PRECAUTIONS	66
SECTION XIII	CLEANING	67
SECTION XIV	SERVICE AND WARRANTY	68
APPENDIX I	STANDBY MODE FOR CONTINUOUS AND V/T MODES	69
APPENDIX II	MAXIMUM FLOW RATES	70
APPENDIX III	DEFINITIONS	73
TABLE 1	ALARM/ALERT GRID	

Section I

INTRODUCTION

Medfusion Syringe Infusion Pump Model 2001 provides a continuous or intermittent infusion of blood, lipids, fluids, antibiotics and other drugs requiring precisely controlled infusion rates.

A unique feature of the 2001 is the custom program mode which allows preselection of certain infusion modes and parameters. Thus, the custom program mode accommodates programming to meet a specific need. Those needs are customized by selection of the number/type of infusion modes, the maximum infusion rate, the alarm volume, the alarm temporary delay time, volume limit, KVO rate, and alarm types. Additionally, this mode offers the health care professional and biomedical engineer a lockout feature which limits access to assure programming reliability.

Model 2001 holds a full complement of disposable syringes (e.g., 1 through 60 ml) for Becton-Dickinson, Monoject and Terumo. The SYRINGE MANUFACTURER and RATE are programmed prior to initiating delivery. For convenience, if desired, the SYRINGE MANUFACTURER can be "custom programmed." The SYRINGE SIZE is automatically selected.

Model 2001, with its state-of-the-art design, is easy to program and monitor while administering intravenous or intra-arterial infusions.

CAUTION:

Federal (USA) law restricts this device to the sale by or on the order of a physician.

IMPORTANT:

Carefully read the entire contents of this manual before attempting to use your Model 2001 Pump, and verify that the SOFTWARE VERSION of the pump and manual are in agreement.

The 2001 has four infusion modes: continuous infusion, volume over time, automatic intermittent, and manual intermittent. The continuous mode is programmed in milliliters per hour. The volume over time mode has parameters of volume in milliliters and time in minutes. The automatic intermittent mode includes parameters of volume to be delivered, the delivery time in minutes, and the time between deliveries in hours and minutes. The manual intermittent mode has program modalities including volume to be delivered, the delivery time in minutes, and the time between deliveries in hours and minutes. The pump alarms when the next delivery is due.

Section II

GENERAL SPECIFICATIONS

Overall Size	4.5" wide X 3.0" high X 7.5" long
Weight	2.5 Pounds
Accuracy	+/-3%, excluding syringe variations
Infusion Modes	Continuous, volume over time, intermittent auto, intermittent manual
Flow Rate	00.01 to 99.99 ml per hour increments of 0.01 OR 0.1 to 356.0 ml per hour in increments of 0.1 (see Appendix I)
Syringe Selection	Three Manufacturers: Becton-Dickinson (B-D); Monoject (Mono); Terumo (Teru) Syringe Sizes B-D - 1,3,5,10,20,30,60 ml Mono - 1,3,6,12,20,35,60 ml Teru - 1,3,5,10,20,30,60 ml
Syringe Fill Volume	All syringe sizes will fill to their maximum stated volumes
Power	AC95-135V; 60HZ DC-Internal rechargeable batteries International voltages available
Recharge Time With Pump On	16 Hours at 25 degrees C
Battery Capacity	At 25 degrees C, a 16 hour charge will operate the pump for at least 10 hours at 5.0 ml per hour with a 60 ml syringe.
Alarms/Alerts	Near Empty Empty Volume Limit Occlusion System Malfunction Low Battery Depleted Battery Syringe Pops Out Invalid Size Invalid Number

289

General Specifications (Cont.)

Alarms/Alerts (Cont.)

Check Clutch
Stop/Program
Deliver
Battery In Use
Battery Charging
(If connected to AC)
Battery Depleted/Plug In AC
Priming
Standby Mode

Total Volume Delivered

000.00 to 999.99 ml increments of
0.01 ml

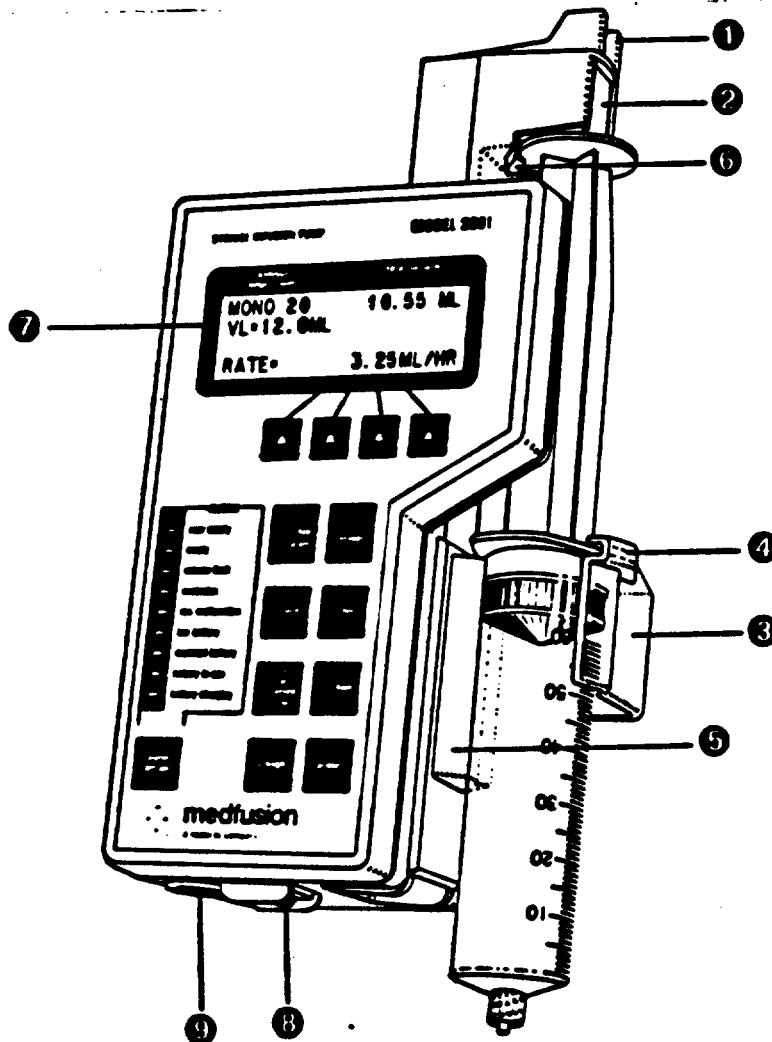
Volume Limit

00.0 to maximum capacity of
syringe size selected in
increments of 0.1 ml

KVO

0.1 to 9.9 ml per hour in
increments of 0.1 ml

Section III
GENERAL DESCRIPTION/DIAGRAM



- | | |
|------------------------------------|-----------------------------|
| 1. CLUTCH LEVER | 6. SYRINGE PLUNGER RETAINER |
| 2. SYRINGE DRIVER | 7. LCD |
| 3. SYRINGE CLAMP (CLEAR) | 8. ON/OFF SWITCH |
| 4. SYRINGE CLAMP GROOVE (RETAINER) | 9. CHARGING RECEPTACLE |
| 5. SYRINGE SADDLE | |

Section IV

CUSTOM PROGRAM MODE

The Custom Program Mode (CP) allows customization by the selection of the infusion modes, the maximum infusion rate, the alarm volume, the alarm temporary delay time, volume limit, KVO rate, and alarm types. Entry into this mode is limited due to the lockout feature. This mode generally is utilized by healthcare professionals and biomedical engineers to initially preprogram the pump prior to routine clinical use. Once the pump is programmed in the CP mode, go to Sections V and VI for normal operating instructions.

STEP 1: ENTERING THE CUSTOM PROGRAM (CP) MODE

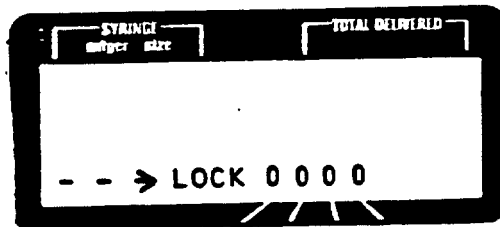
1A.



To enter the CP Mode, press and hold down at the same time the SELECT and ENTER keys then turn the pump ON with the power switch.

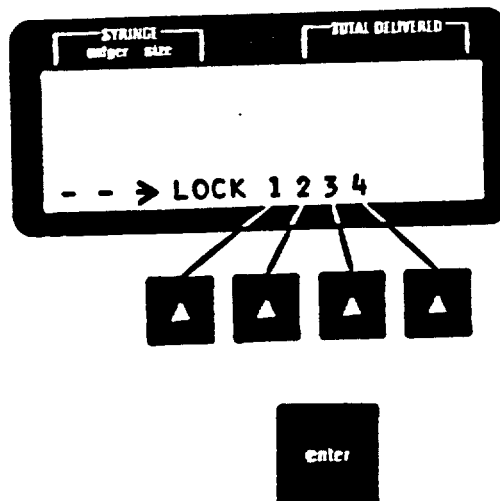
The LCD display should be blank.

1B. Requesting Lockout Access Code



Release the SELECT and ENTER keys to visualize the LOCK CODE.

1C. Enter Lockout Access Code



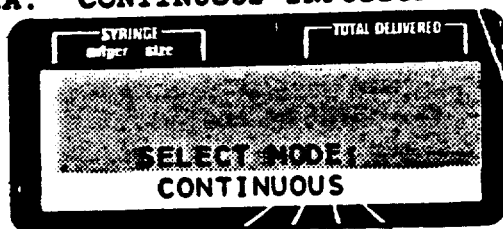
Program the access code 1234 by using the appropriate rate keys.

Press ENTER to enter the code. The pump will automatically advance to the CP Mode if a valid code is entered.

An erroneous code denies access to the CP Mode.

STEP 2: PREPROGRAMMING DELIVERY MODES

2A. CONTINUOUS INFUSION



The flashing LCD identifies the CONTINUOUS pump delivery mode.



Press ENTER to access the CONTINUOUS mode.

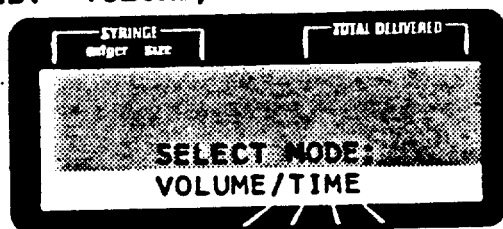


OR

Press SELECT to eliminate access to the CONTINUOUS mode.

The LCD automatically advances to the next choice.

2B. VOLUME/TIME



The flashing LCD identifies the VOLUME/TIME pump delivery mode.



Press ENTER to access the VOLUME/TIME mode.

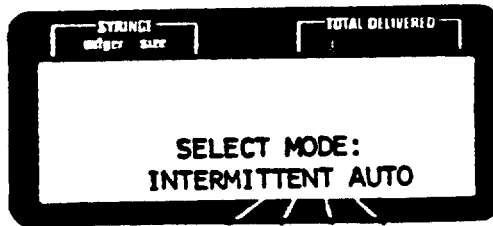
OR

Press SELECT to eliminate access to the VOLUME/TIME mode.

The LCD automatically advances to the next choice.

23

2C. INTERMITTENT AUTO



The flashing LCD identifies the INTERMITTENT AUTOMATIC pump delivery mode.

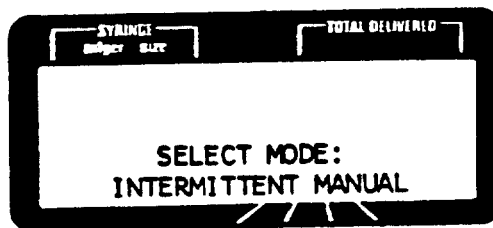
Press ENTER to access the INTERMITTENT AUTOMATIC mode.

OR

Press SELECT to eliminate access to the INTERMITTENT AUTOMATIC mode.

The LCD automatically advances to the next choice.

2D. INTERMITTENT MANUAL



The flashing LCD identifies the INTERMITTENT MANUAL mode.

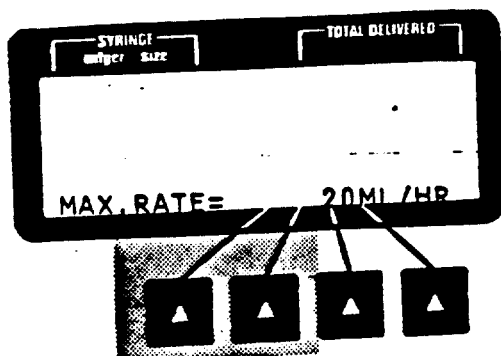
Press ENTER to access the INTERMITTENT MANUAL mode.

OR

Press SELECT to eliminate access to the INTERMITTENT MANUAL mode.

The LCD automatically advances to the next screen.

STEP 3: PROGRAMMING MAXIMUM RATE (ONLY IF CONTINUOUS MODE WAS SELECTED)

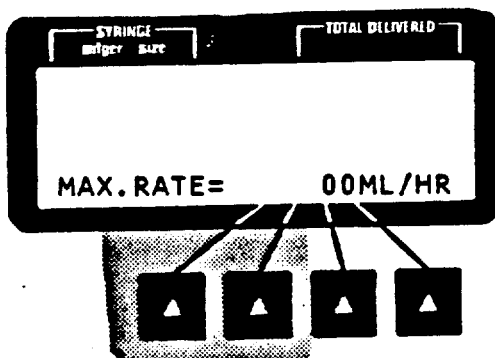


Programming a MAX RATE:

- 1) allows programming to hundredths of an ml per hour for all syringe sizes

and

- 2) limits the acceptable programmable rate in the CONTINUOUS MODE to the value programmed.



No value entry for MAX RATE (i.e., a setting of 00) limits the minimum rate to tenths for syringe sizes larger than 6 ml.



Entry of a value sets the MAX RATE in the CONTINUOUS MODE only.

The LCD automatically advances to the next screen.

STEP 4: PROGRAMMING OPTIONS

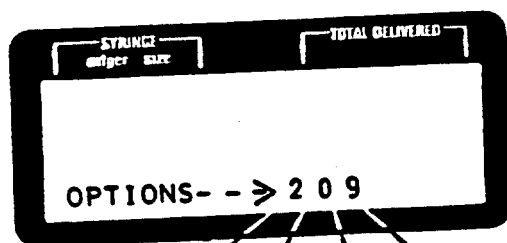
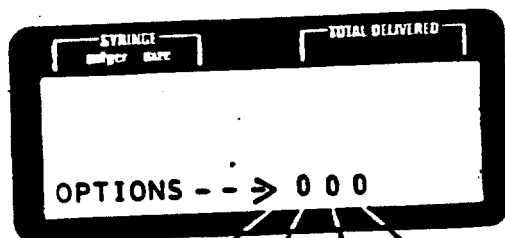


Table I - Programming Options (see next page) assists in custom programming the pump for any combination of the following: Volume Limit (yes or no), KVO (yes or no), alarm option (all or some), alarm volume (soft or loud), alarm temporary off (5 min. or 60 min.) and syringe manufacturer (fixed or variable). For example, option number 209 refers to:

Volume Limit - yes	-	128
KVO - yes	-	64
Alarm option - all	-	0
Alarm volume - Loud	-	16
Alarm delay - 5 min	-	0
Manufacturer - Mono	-	<u>1</u>
		209

Press the appropriate RATE SELECTION key(s) to program the OPTION number.

Press Enter to confirm your OPTIONS and the LCD will automatically exit the CP mode. Refer to Section V, page 11 for further user instructions.

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TABLE I
PROGRAMMING OPTIONS

<u>Features</u>	<u>Choices</u>	
1. Volume Limit (VL)	No = 0; Yes = 128	_____
2. KVO	No = 0; Yes = 64	_____
3. Alarm Option	All = 0; Some = 32	_____
4. Alarm Volume	Soft = 0; Loud = 16	_____
5. Alarm Temporary Delay Time	5 min = 0; 1 hr = 8	_____
6. Syringe Manufacturer	Variable = 4 Fixed Teru = 2 Fixed Mono = 1 Fixed B-D = 0	_____
Options Total =		_____

For example, if one wished to preprogram a pump for:

- 1. No volume limit = 0
- 2. No KVO = 0
- 3. All alarms = 0
- 4. Loud volume = 16
- 5. 5 min delay time = 0
- 6. Fixed Mono = 1

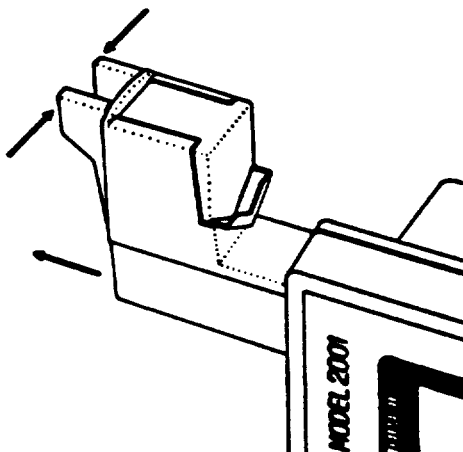
Simply program 17 for custom program options.

Alarm option. Selection of "ALL" programs the alarms to work as described. Selection of "SOME" silences the audio component for all type 1 and 2 alarms including STOP/PROGRAM, NEAR EMPTY, EMPTY and VOLUME LIMIT. Type 3 alarms work as described. Refer to Section VIII, page 58.

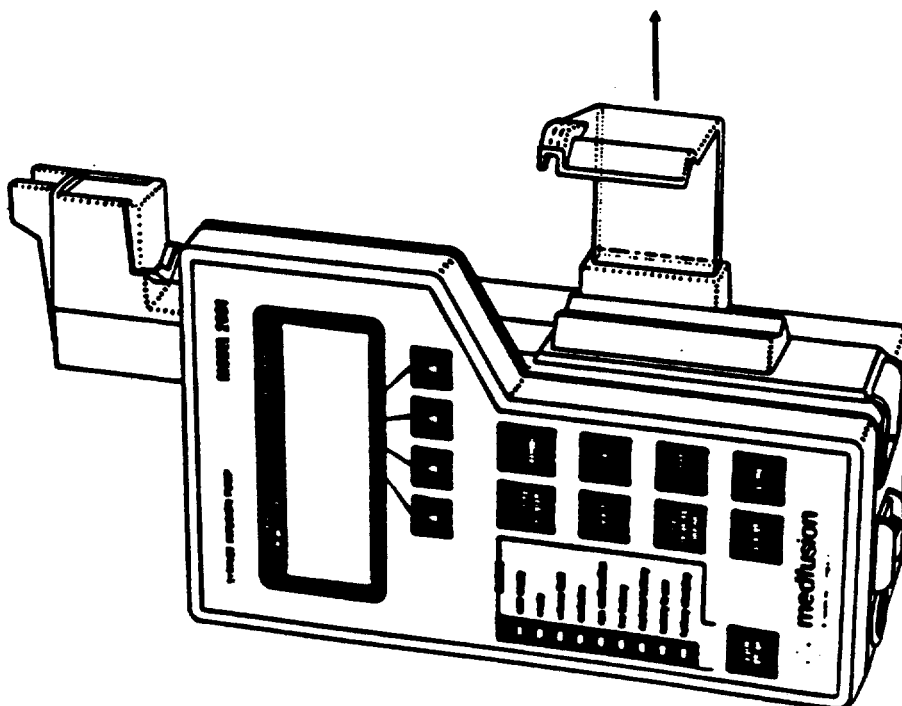
Section V
OPERATING INSTRUCTIONS

STEP 1: SYRINGE LOADING

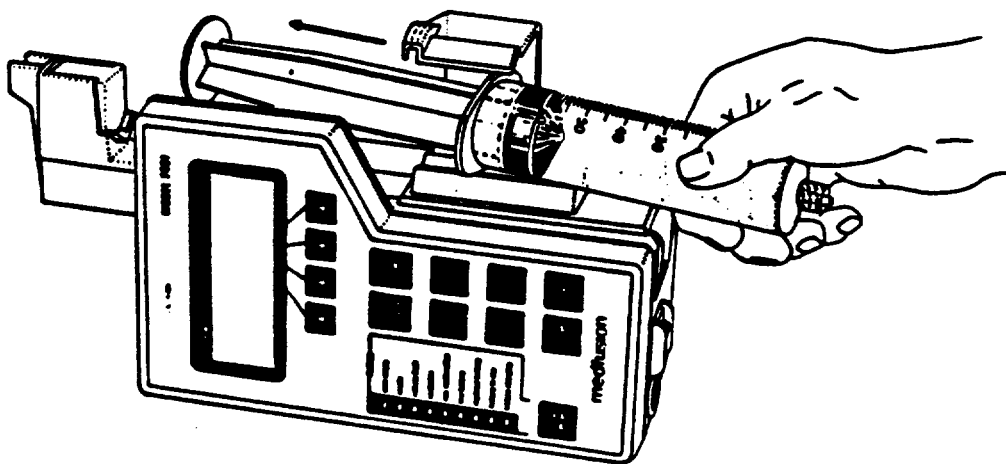
- 1A. Pinch together the CLUTCH LEVER, release the clutch and pull the SYRINGE DRIVER outward until it reaches the end of its track.



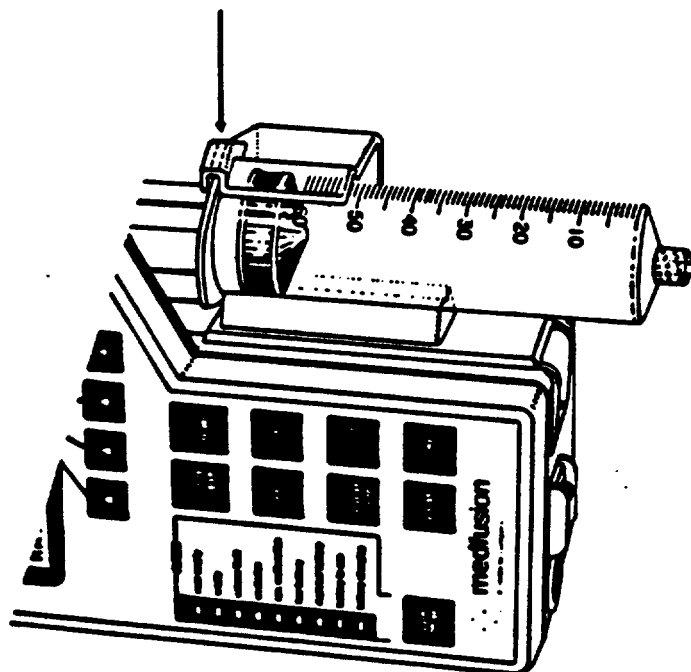
- 1B. Grasp the clear SYRINGE CLAMP, pull upward allowing room for the syringe in the SYRINGE SADDLE.



1C. Insert the syringe plunger first.

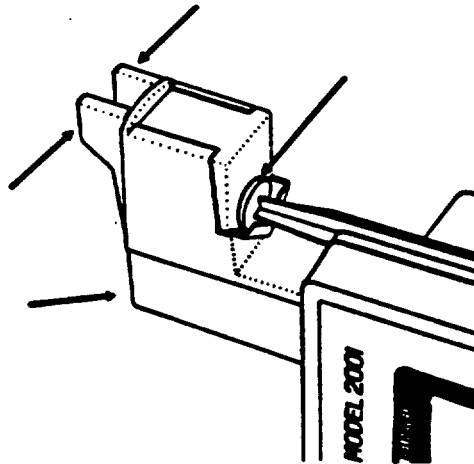


1D. Make sure the syringe finger tabs are retained by the groove on the clear syringe clamp.

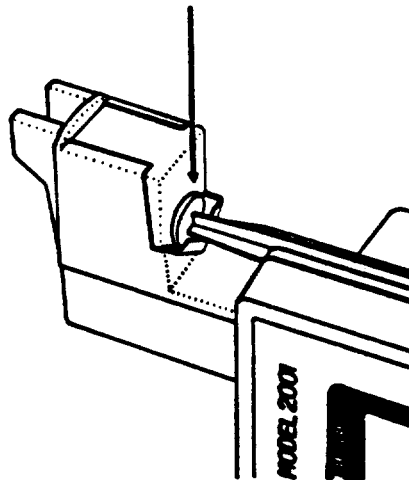


A handwritten signature or mark in the bottom right corner of the page.

- 1E. Pinch together the CLUTCH LEVER and move the SYRINGE DRIVER forward until the SYRINGE DRIVER contacts the end of the DISPOSABLE SYRINGE.



- 1F. Insert the end of the SYRINGE PLUNGER into the SYRINGE PLUNGER RETAINER thus holding it in place.



IMPORTANT: Make sure the CLUTCH LEVER snaps into its fully extended operating position.

STEP 2: TURNING THE PUMP "ON"; REVIEWING THE CUSTOM PROGRAMMED FEATURES AND PUMP SELF TEST

- 2A. The main power switch is located on the end of the pump. Switch it to its "ON" position (e.g., 0=Off; 1=On). NOTE: Make sure the power cord is plugged into an electrical outlet (unless battery power is required).

SYRINGE ml/gal	DATE	TOTAL DELIVERED
VER 1.2 OPTIONS=***		
VL KVO 25 BAT V.=*,*		
ALARM=LOUD 5MIN ALL		
SYSTEM TEST		

When "ON," the LCD (Liquid Crystal Display) displays the following information:

Line 1 - Software version and a three digit number that defines the custom program options (see Table I, page 10).

SYRINGE ml/gal	DATE	TOTAL DELIVERED
VER 1.2 OPTIONS=***		
VL KVO 25 BAT V.=*,*		
ALARM=LOUD 5MIN ALL		
SYSTEM TEST		

Line 2 - A VL indicates a VOLUME LIMIT was custom programmed. A KVO indicates a KVO was custom programmed and a two digit number indicates MAXIMUM FLOW RATE for the continuous mode was custom programmed. The BATTERY VOLTAGE appears as a two digit number.

SYRINGE ml/gal	DATE	TOTAL DELIVERED
VER 1.2 OPTIONS=***		
BAT V.=*,*		
ALARM=LOUD 5MIN ALL		
SYSTEM TEST		

NOTE: A blank LCD for VL, KVO and MAXIMUM FLOW RATE indicates these features have not been custom programmed.

SYRINGE ml/gal	DATE	TOTAL DELIVERED
VER 1.2 OPTIONS=***		
VL KVO 25 BAT V.=*,*		
ALARM=LOUD 5MIN ALL		
SYSTEM TEST		

Line 3 - Alarms that were custom programmed appear. The first choice is either LOUD or SOFT, the second is the TEMPORARY ALARM DELAY TIME which is either 5 MIN or 1 HR, and the third is ALARM OPTIONS which is either ALL or SOME.

SYRINGE output size		TOTAL DELIVERED	
VER 1.2	OPTIONS=xxx		
VL KVO	BAT V.=x.x		
ALARM=LOUD 5MIN ALL			
LED/ALARM TEST			

The audio alarm sounds. Line 4: The LCD states "SYSTEM TEST" then it states "LED/ALARM TEST" and all LEDs (Light Emitting Diode) except the BATTERY CHARGING and SYSTEM MALFUNCTION briefly light. Note: The Battery In Use, STOP/PROGRAM, and DELIVER LEDs will blink.

ALARMS		stop program		deliver	
<input type="checkbox"/>	near empty				
<input type="checkbox"/>	empty				
<input type="checkbox"/>	volume limit				
<input type="checkbox"/>	occlusion				
<input type="checkbox"/>	sys. malfunction				
<input type="checkbox"/>	low battery				
<input type="checkbox"/>	depleted battery				
<input type="checkbox"/>	battery in use				
<input type="checkbox"/>	battery charging				

SYRINGE output size		TOTAL DELIVERED	
VER 1.2	OPTIONS=xxx		
VL KVO	BAT V.=x.x		
ALARM=LOUD 5MIN ALL			
SYS MAL TEST			

The pump performs a System Malfunction Test by lighting the System Malfunction LED and sounding the audio alarm. Line 1 through 3 continue to display the information described above.

ALARMS	
<input type="checkbox"/>	near empty
<input type="checkbox"/>	empty
<input type="checkbox"/>	volume limit
<input type="checkbox"/>	occlusion
<input type="checkbox"/>	sys. malfunction
<input type="checkbox"/>	low battery
<input type="checkbox"/>	depleted battery
<input type="checkbox"/>	battery in use
<input type="checkbox"/>	battery charging

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STEP 3: PROGRAMMING THE 2001 - INTRODUCTION

The program key "LED" (Light Emitting Diode) blinks, and a slow intermittent beep (#1) sounds to indicate the Program Mode. (The alarm temporarily silences by pressing the ALARM OFF/ON Key once.) Program or function changes occur only in the Stop/Program Mode.

A single audio peck indicates a valid key press. (Occurs even when the audio is turned off.)

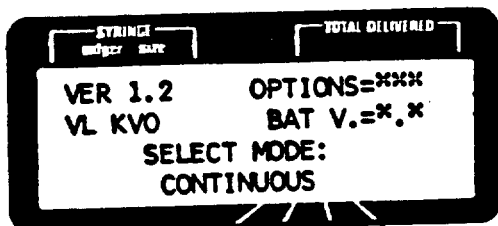
- 3A. Accessing the desired Infusion Mode (only if more than one mode was custom programmed).

The Model 2001 employs sequential programming. The operator knows what selections can be made or programmed because they flash.

NOTE: The infusion modes appear in the following order, provided they were all custom programmed: CONTINUOUS, VOLUME/TIME, INTERMITTENT AUTO and INTERMITTENT MANUAL. These parameters do not appear if not custom programmed.

"PRESENT MODE IS" on the third line of the LCD indicates only one mode was custom programmed. Refer to Section VI, page 19.

- 3B. Continuous Mode. CONTINUOUS stands for Continuous Infusion.



NOTE: VL (Volume Limit) and KVO (keep vein open) appear on the LCD only if they were custom programmed. No maximum rate was custom programmed (the space is blank).

Press ENTER to use this mode. The pump automatically advances to CONTINUOUS program. See Section VI, page 19.

OR

Press SELECT to access other custom programmed infusion modes. The next choice appears sequentially (e.g., VOLUME/TIME, INTERMITTENT AUTO, INTERMITTENT MANUAL).

241

3C. Volume/Time

SYRINGE		TOTAL DELIVERED	
ml/hr	size		
VER 1.2		OPTIONS=***	
VL KVO		BAT V.=*.x	
SELECT MODE:			
VOLUME/TIME			

enter

Press ENTER to use this mode. The pump automatically advances to the VOLUME OVER TIME program. See Section VI, page 19.

OR

select

Press SELECT to access other custom programmed infusion modes. The next choice appears sequentially (e.g., INTERMITTENT AUTO, INTERMITTENT MANUAL, CONTINUOUS).

3D. Intermittent Auto

SYRINGE		TOTAL DELIVERED	
ml/hr	size		
VER 1.2		OPTIONS=***	
VL KVO		BAT V.=*.x	
SELECT MODE:			
INTERMITTENT AUTO			

enter

Press ENTER to use this mode. The pump automatically advances to the INTERMITTENT AUTO program. See Section VI, page 19.

OR

select

Press SELECT to access other custom programmed infusion modes. The next choice appears sequentially (e.g., INTERMITTENT MANUAL, CONTINUOUS, VOLUME/TIME).

3E. Intermittent Manual

SYRINGE ml/hr	TOTAL DELIVERED
VER 1.2	OPTIONS=***
VL KVO	BAT V.=*,*
SELECT MODE:	
INTERMITTENT MANUAL	



Press ENTER to use this mode.
The pump automatically
advances to the INTERMITTENT
MANUAL program. See Section
VI, page 19.

OR



If another preprogrammed
infusion mode is desired,
press SELECT and the next
choice will appear (e.g.,
CONTINUOUS, VOLUME/TIME,
INTERMITTENT AUTO).

243

SECTION VI

USER MODES

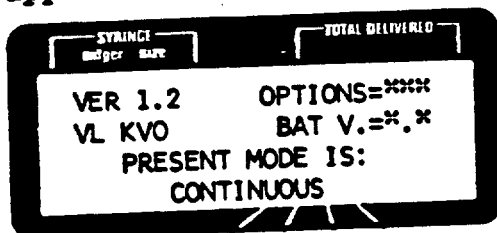
Introduction

Go to the appropriate section for the mode you wish to program.

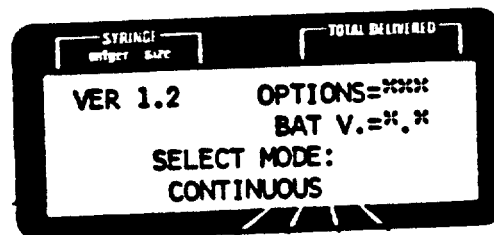
Continuous Infusion	Pages 19-26
Volume/Time	Pages 27-33
Intermittent Auto	Pages 34-44
Intermittent Manual	Pages 45-55

STEP 1: CONTINUOUS INFUSION

When the pump is turned ON, lines 3 and 4 of the LCD display appear as follows:



OR

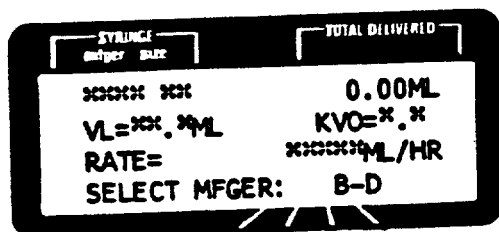


If "PRESENT MODE IS" appears, no other modes were custom programmed.

If "SELECT MODE" appears, other infusion modes can be selected by using the select key (see Section V, Step 3, page 16-18). To select CONTINUOUS, press ENTER.

STEP 2: PROGRAMMING SYRINGE MANUFACTURER (CUSTOM PROGRAMMABLE)

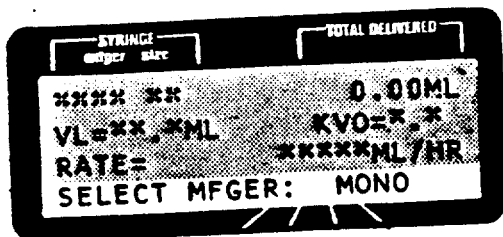
NOTE: If a syringe manufacturer is custom programmed, the pump automatically advances to LOAD SYRINGE. Entry into the custom program mode allows a syringe manufacturer change.



Press SELECT key to make the choices appear on the LCD. Repeated presses of the SELECT key display the available choices. For example, B-D refers to Becton-Dickinson, Mono refers to Monoject, while Teru refers to Terumo.



244

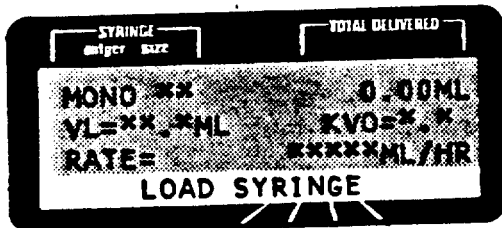


Press ENTER to program your selection. NOTE: The SYRINGE MANUFACTURER appears on the LCD and the pump automatically advances to the next programmable item.

NOTE: Turn the main power off and start over to correct an inadvertent misentry of the Syringe Manufacturer. A correction is possible only if SELECT MANUFACTURER appears on the LCD.

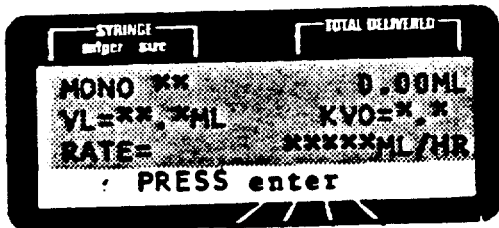
IMPORTANT: Verify that the syringe manufacturer on the LCD is the same as the syringe in use. Failure to use the listed manufacturer could result in inaccurate delivery.

STEP 3: PROGRAMMING SYRINGE SIZE



The fourth line of the LCD flashes "LOAD SYRINGE -- PRESS enter."

If the syringe is not already loaded onto the pump, load the syringe as instructed (see Section V, page 11-13).



Once the syringe is properly loaded, press the ENTER key. The pump will automatically enter the correct syringe size and advance to the next programmable item.

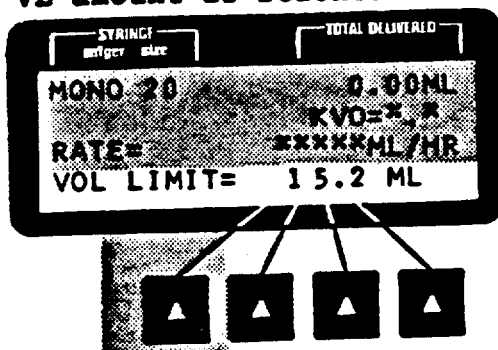
IMPORTANT: Always confirm that the syringe size stated on the LCD agrees with the size of the syringe loaded on the pump. Failure to do so could result in inaccurate delivery.

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STEP 4A: PROGRAMMING THE VOLUME LIMIT (CUSTOM PROGRAMMABLE)

If VOL LIMIT does not appear on the LCD, it was not custom programmed; skip to Step 6.

The VOLUME LIMIT (VL) feature allows delivery of a specific preprogrammed fluid volume from any size syringe. Therefore, the volume in the syringe can be greater than the volume to be infused. The pump stops automatically when the VL amount is reached.



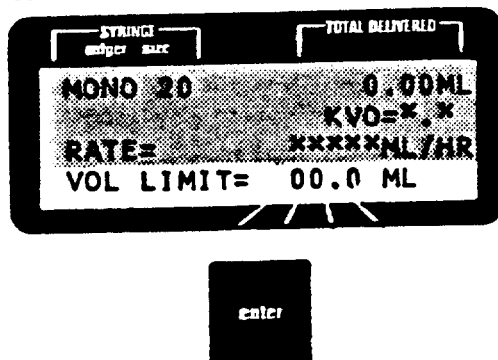
Program the VL with the RATE SELECTION key(s). Continuously pressing the RATE SELECTION key(s) automatically advances the number.



Press ENTER to program the desired VL. The LCD automatically advances.

NOTE: If the VL exceeds the syringe capacity, the LCD will display INVALID NUMBER and show the highest possible VL programmable for the syringe selected.

STEP 4B: PROGRAMMING NO VOLUME LIMIT.



A VL set at 00.0 eliminates VL as a previously programmed feature for this infusion. Press ENTER.



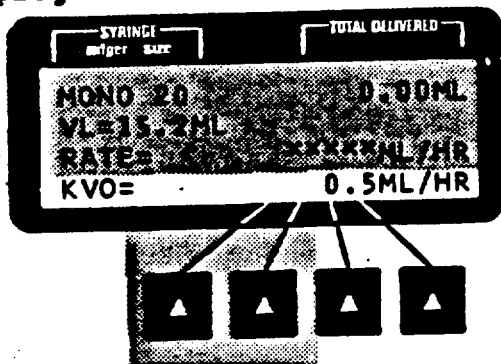
The VL disappears from the LCD for this infusion and the LCD automatically advances.

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**STEP 5A: PROGRAMMING KVO (KEEP VEIN OPEN) RATE
(CUSTOM PROGRAMMABLE)**

The KVO feature allows delivery of a KVO rate after a specified VOLUME LIMIT is administered.

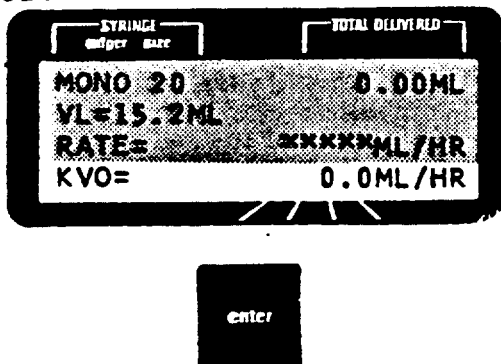
NOTE: If a VL is not programmed, a KVO cannot be programmed. The LCD skips to programming RATE, step 6.



Program the KVO with the RATE SELECTION keys. Continuously pressing the RATE SELECTION key(s) automatically advances the number.

Press enter to program desired KVO. The LCD automatically advances.

STEP 5B: PROGRAMMING NO KVO RATE



A KVO set at 0.0 eliminates KVO as a previously programmed feature for this infusion. Press ENTER.

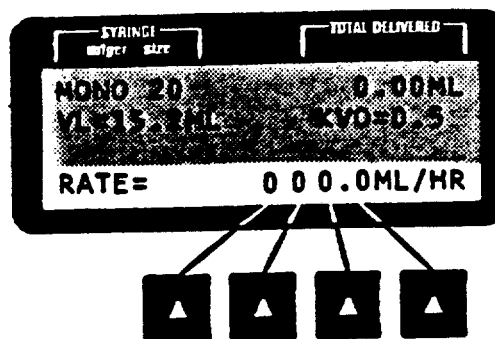
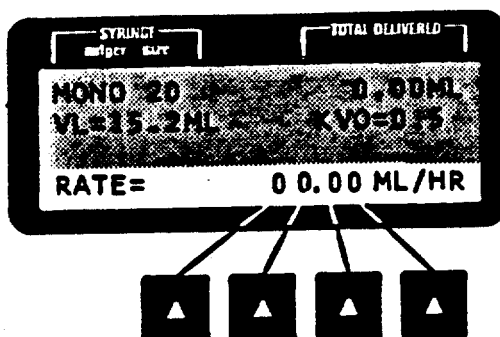
The KVO disappears from the LCD for this infusion and the LCD automatically advances.

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STEP 6: PROGRAMMING RATE

NOTE: If a MAXIMUM RATE is custom programmed, the decimal point for all size syringes will be in 0.01 (hundredths) of an ml per hour as shown below.

NOTE: If a MAXIMUM RATE is not custom programmed, the decimal point for all syringe sizes greater than 6 ml will be in tenths (e.g., 0.1) as shown below and for syringes 6 ml and smaller in hundredths (0.01) of an ml per hour as shown below.



To program a rate, press the RATE SELECTION key(s) located beneath the rate. The SELECT key does not program a rate. **NOTE:** Continuously pressing the RATE SELECTION key(s) automatically advances the number.



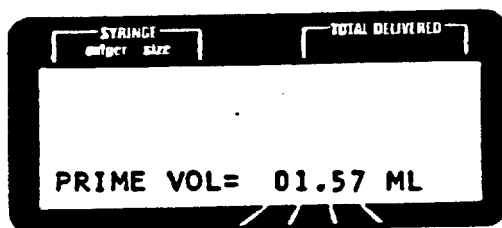
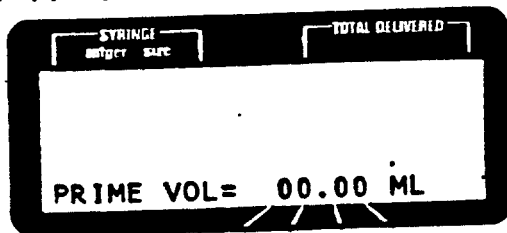
Press ENTER to enter the desired rate.

No information on the LCD flashes. When the display is solid (not flashing), the operator can PRIME and/or commence DELIVERY.

NOTE: INVALID NUMBER displays on the LCD when an invalid rate entry occurs followed by the highest possible rate programmable for the syringe selected (see Appendix I, page 68).

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STEP 7: PRIMING



Push and hold the PRIME key to purge air from the administration set. The LCD states "PRIME VOL = 00.00 ML" and the pump runs at its fastest rate. After approximately 16 seconds elapses, a continuous tone (#3) sounds. However, the pump continues to prime when the key is held down.

NOTE: The amount delivered while priming is NOT counted by the TOTAL VOLUME DELIVERED counter. However, the amount delivered is shown on the prime volume counter.

NOTE: The PRIME function only activates when the pump is in the STOP/PROGRAM MODE and all other functions are entered (e.g., Syringe Manufacturer, Syringe Size, Volume Limit, KVO and Rate).

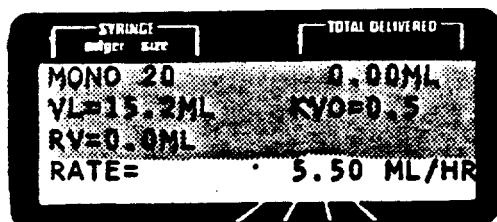
IMPORTANT: The PRIME function should always be utilized when placing a newly filled syringe on the pump or when attaching an infusion set.

IMPORTANT: When PRIMING, if a small bore extension set is being used (i.e., Medfusion's Mini-Vol Set), the OCCLUSION ALARM may actuate. Continue to press PRIME. The OCCLUSION ALARM should clear.

Several attempts may be required to fully PRIME the infusion set. To simplify PRIMING a small bore set, intermittently press and release the PRIME key versus pressing and holding it continuously. Medfusion's slightly larger tubing eliminates the above occurrence.

245

STEP 8A: DELIVERY



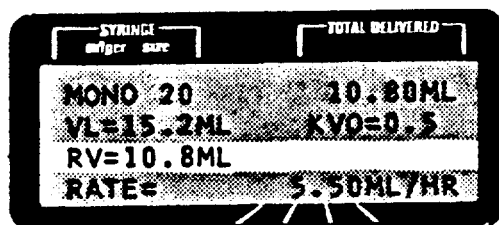
Press the DELIVER key to begin the infusion. The LCD will not flash and the green LED DELIVER light begins to blink.

The RV will not appear on the LCD until delivery begins.



In the DELIVERY MODE, all keys are inactive except the ALARM ON/OFF key and the STOP/PROGRAM key.

STEP 8B: RUNNING VOLUME (ONLY IF VL IS PROGRAMMED)



The RUNNING VOLUME (RV) in tenths of a ml is displayed on the LCD.

NOTE: The RV records volume delivered since the last VL reset. By comparing the RV to the VL, one can determine how much more fluid must be delivered before reaching the VL.

The RV is reset to zero when any of the following occur -
Change in syringe size, Empty alarm, Reprogram the VL, Reset TOT VOL DEL counter to zero, when the VL is reached and when prime is used.



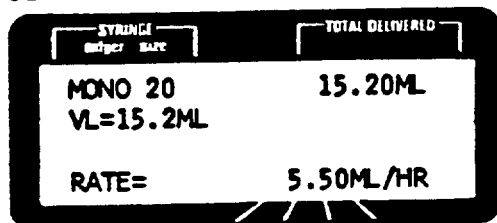
STEP 9A: STOP DELIVERY



Press the STOP/PROGRAM key to stop the infusion. The STOP/PROGRAM LED blinks and a slow intermittent #1 audio alarm sounds.

NOTE: Alarms (e.g., occlusion, depleted battery, syringe pops out) interrupt delivery. Correct the alarm and press DELIVER key to resume.

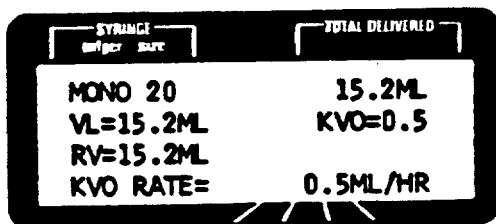
STEP 9B: END OF DELIVERY - VOLUME LIMIT WITHOUT KVO



When the programmed VL is reached, the number 2 audio alarm sounds, the VL LED lights, the RV=VL and the STOP/PROGRAM LED blinks, indicating delivery cessation.

NOTE: The VL equals the TOTAL VOLUME DELIVERED readout only during the administration of the first infusion. To continue the infusion, press DELIVER. The VOLUME LIMIT ALARMS reset to zero and resume when the programmed amount is again delivered. For example, if two VL amounts are delivered, the TOTAL VOLUME DELIVERED amount equals twice the VL amount.

STEP 9C: END OF DELIVERY - VOLUME LIMIT WITH KVO



When the programmed VL is reached (VL=RV), the pump automatically switches to the KVO rate, the VOLUME LIMIT LED lights and a type 1 audio alarm sounds.

The pump continues delivery until the STOP/PROGRAM key is pressed or until the EMPTY alarm sounds.

STEP 10: PROGRAMMING STANDBY TIME

See APPENDIX I for specific details regarding this feature.

est

STEP 1: VOLUME/TIME

Introduction

The VOLUME OVER TIME mode requires entry of at least two infusion parameters -- the desired DOSE VOLUME (DV) and the desired DELIVERY TIME (DT). This mode is most useful in delivery of a single dose. The rate in ml per hour calculates automatically. The DOSE VOLUME becomes the VOLUME LIMIT (VL); therefore, a VL can not be programmed. However, a KVO rate can be custom programmed. Use this mode when one needs to deliver a single dose over time versus using the CONTINUOUS MODE where the rate must be calculated.

The following examples assume all available custom programmable items (parameters) are utilized (e.g., VL, KVO). When the pump is turned ON, lines 3 and 4 of the LCD display as follows:

SYRINGE mfgcr rate	TOTAL DELIVERED
VER 1.2	OPTIONS=***
VL KVO	BAT V.=*.x
PRESENT MODE IS: VOLUME/TIME	

If "PRESENT MODE IS" appears, no other infusion modes were custom programmed.

SYRINGE mfgcr rate	TOTAL DELIVERED
VER 1.2	OPTIONS=***
VL KVO	BAT V.=*.x
SELECT MODE: VOLUME/TIME	

If "SELECT MODE" appears, other infusion modes can be selected by using the SELECT key. To select VOLUME/TIME, press ENTER. (See Section V, Step 3, page 16-18).

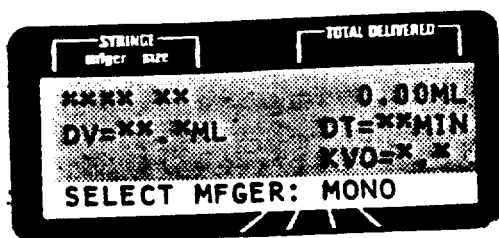
STEP 2: PROGRAMMING SYRINGE MANUFACTURER

NOTE: If a SYRINGE MANUFACTURER is custom programmed, the pump automatically advances to LOAD SYRINGE. Entry into the custom program mode allows a syringe manufacturer change.

SYRINGE mfgcr rate	TOTAL DELIVERED
XXXXX XXX	0.00ML
DV=XX.XML	DT=XXMIN
	KVO=*.x
SELECT MFGER:	B-D

select

Press SELECT key to make the choices appear on the LCD. Repeated presses of the SELECT key display the available choices. For example, B-D refers to Becton-Dickinson, Mono refers to Monoject and Teru refers to Terumo.

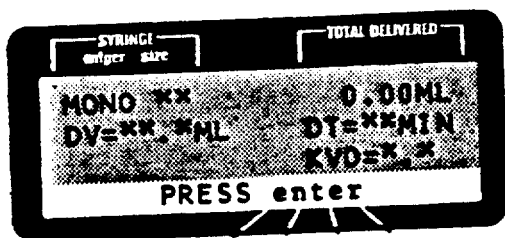
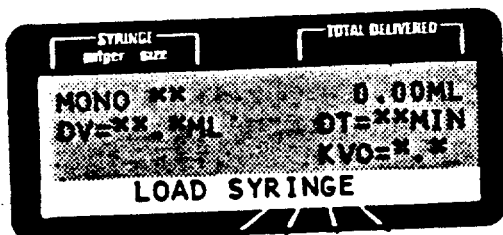


Press ENTER to program your selection. NOTE: The SYRINGE MANUFACTURER appears on the LCD and the pump automatically advances to the next programmable item.

NOTE: Turn the main power off and start over to correct an inadvertent misentry of the Syringe Manufacturer. A correction is possible only if SELECT MANUFACTURER appears on the LCD.

IMPORTANT: Verify that the syringe manufacturer on the LCD is the same as the syringe in use. Failure to use the listed manufacturer could result in inaccurate delivery.

STEP 3: PROGRAMMING SYRINGE SIZE



The fourth line of the LCD will flash "LOAD SYRINGE" -- "PRESS enter."

If the syringe is not already loaded onto the pump, load the syringe as instructed (see Section V, page 11-13).

Once the syringe is properly loaded, press the ENTER key. The pump will automatically enter the correct syringe size and advance to the next programmable item.

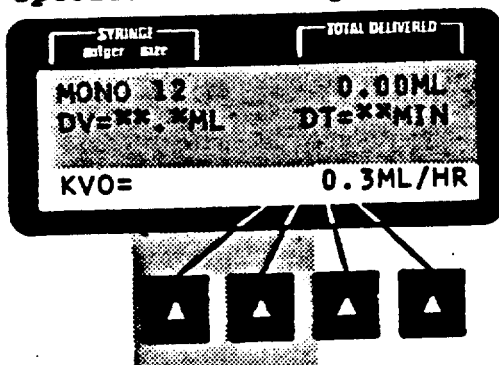
IMPORTANT: Always confirm that the syringe size stated on the LCD agrees with the size of the syringe loaded on the pump. Failure to do so could result in inaccurate delivery.

STEP 4: PROGRAMMING THE VOLUME LIMIT (CUSTOM PROGRAMMABLE)

With this infusion mode (V/T), the VOLUME LIMIT (VL) is automatically programmed but the VL does not appear on the LCD.

STEP 5A: PROGRAMMING KVO (KEEP VEIN OPEN) RATE (CUSTOM PROGRAMMABLE)

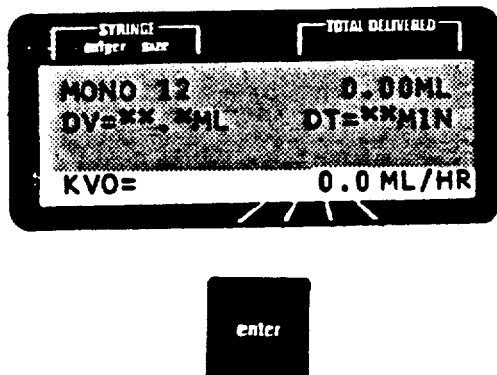
The KVO feature allows delivery of a KVO rate after the specified delivery is administered.



Program the KVO with the RATE SELECTION key(s). Continuously pressing the RATE SELECTION key(s) automatically advances the number.

Press ENTER to program desired KVO. The LCD automatically advances.

STEP 5B: PROGRAMMING NO KVO RATE



A KVO set at 0.0 eliminates KVO as a previously programmed feature for this infusion. Press ENTER.

The KVO disappears from the LCD for this infusion and the LCD automatically advances.

STEP 6: PROGRAMMING DOSE VOLUME (DV)

SYRINGE		TOTAL DELIVERED	
id	rate		
MONO 12		0.00ML	
		DT= 30 MIN	
		KVO=0.3	
DOSE VOL.=		00.0 ML	

Press the appropriate RATE SELECTION key(s) to program a DOSE VOLUME (DV). NOTE: Continuously pressing the RATE SELECTION key(s) automatically advances the number.

SYRINGE		TOTAL DELIVERED	
id	rate		
MONO 12		0.00ML	
		DT= 30 MIN	
		KVO=0.3	
DOSE VOL.=		10.0 ML	



Press ENTER key to enter the desired DV. The LCD automatically advances.

STEP 7: PROGRAMMING DELIVERY TIME (DT)

SYRINGE		TOTAL DELIVERED	
id	rate		
MONO 12		0.00ML	
DV=10.0ML			
		KVO=0.3	
DEL. TIME =		00:00	

Press the appropriate RATE SELECTION key(s) to program a DELIVERY TIME (DT). NOTE: Continuously pressing the RATE SELECTION key(s) automatically advances the number.

SYRINGE		TOTAL DELIVERED	
id	rate		
MONO 12		0.00ML	
DV=10.0ML			
		KVO=0.3	
DEL. TIME =		01:30	



Press ENTER key to enter the desired DT. The LCD automatically advances.

NOTE: INVALID NUMBER displays on the LCD when an invalid rate entry occurs. The fastest possible infusion time will appear for the DV selected.

SYRINGE ml/hr		TOTAL DELIVERED	
MONO 12	0.00ML		
DV=10.0ML	DT=01:30		
	KVO=0.3		
RATE=	6.667ML/HR		

The pump automatically calculates the rate and all information on the LCD is solid (not flashing). Options are to PRIME and/or begin DELIVERY.

STEP 8: PRIMING

SYRINGE ml/hr		TOTAL DELIVERED	
PRIME VOL= 00.00 ML			

SYRINGE ml/hr		TOTAL DELIVERED	
PRIME VOL= 01.57 ML			



Push and hold the PRIME key to purge air from the administration set. The LCD states "PRIME VOL = 00.00 ML" and the pump runs at its fastest rate. After approximately 16 seconds elapses, a continuous tone (#3) sounds. However, the pump continues to prime when the key is held down.

NOTE: The amount delivered while priming is NOT counted by the TOTAL VOLUME DELIVERED counter. However, the amount delivered is shown on the prime volume counter.

NOTE: The PRIME function only activates when the pump is in the STOP/PROGRAM MODE and all other functions are entered (e.g., Syringe Manufacturer, Syringe Size, Volume Limit, KVO and Rate).

IMPORTANT: The PRIME function should always be utilized when placing a newly filled syringe on the pump or when attaching an infusion set.

IMPORTANT: When PRIMING, if a small bore extension set is being used (i.e., Medfusion's Mini-Vol Set), the OCCLUSION ALARM may actuate. Continue to press PRIME. The OCCLUSION ALARM should clear.

Several attempts may be required to fully PRIME the infusion set. To simplify PRIMING a small bore set, intermittently press and release the PRIME key versus pressing and holding it continuously. Medfusion's slightly larger tubing eliminates the above occurrence.

STEP 9A: DELIVERY

SYRINGE		TOTAL DELIVERED	
subject	size		
MONO 12		0.00ML	
DV=10.0ML		DT=01:30	
RV=0.0ML		KVO=0.3	
RATE=		6.667ML/HR	



Press the DELIVER key to begin the infusion. The LCD will not flash and the green LED DELIVER light begins to blink.

The RV will not appear on the LCD until delivery begins.

In the DELIVERY MODE, all keys are inactive except the ALARM ON/OFF key and the STOP/PROGRAM key.

STEP 9B: RUNNING VOLUME

SYRINGE		TOTAL DELIVERED	
subject	size		
MONO 12		9.60ML	
DV=10.0ML		DT=01:30	
RV=9.6ML		KVO=0.3	
RATE=		6.667ML/HR	



The RUNNING VOLUME (RV) in tenths of a ml will be displayed on the LCD.

NOTE: The RV records how much of the DOSE VOLUME (e.g., VOLUME LIMIT) has been delivered.

The RV is reset to zero when any of the following events occur - Change in syringe size, Empty alarm, Reprogram the DL, reset TOT VOL DEL counter to zero, when the VL is reached and when Prime is used.

STEP 10A: STOP DELIVERY

SYRINGE		TOTAL DELIVERED	
subject	size		
MONO 12		9.60ML	
DV=10.0ML		DT=01:30	
RATE=		6.667ML/HR	



Press the STOP/PROGRAM key to stop the infusion. The STOP/PROGRAM LED blinks and a slow intermittent #1 audio alarm sounds.

NOTE: Alarms (e.g., occlusion, depleted batteries, syringe pops out) interrupt delivery. Correct the alarm and press DELIVER key to resume. The remaining DV is given at the proper rate.

STEP 10B: -- END OF DELIVERY WITHOUT KVO

SYRINGE		TOTAL DELIVERED	
id	rate		
MONO 12		10.00ML	
DV=10.0ML		DT=01:30	
RATE=		6.667ML/HR	

When the DOSE VOLUME (DV) is reached, the number 2 audio alarm sounds, the VL LED lights, the RV=DV, and the STOP/PROGRAM LED blinks indicating delivery cessation.



NOTE: The DV only equals the TOTAL VOLUME DELIVERED readout during the administration of the first infusion. To continue the infusion, press DELIVER. The VOLUME LIMIT ALARMS reset to zero (RV=0.0ml) and come back on when the programmed amount is delivered. For example, if two DV amounts are delivered, the TOTAL VOLUME DELIVERED amount will equal twice the DV amount.

STEP 10C: END OF DELIVERY WITH KVO

SYRINGE		TOTAL DELIVERED	
id	rate		
MONO 12		10.00ML	
DV=10.0ML		DT=01:30	
RV=10.0ML		KVO=0.3	
KVO RATE=		0.3ML/HR	

When the programmed DV is reached, the pump automatically switches to the KVO rate, the VOLUME LIMIT LED lights (RV=DV) and a type 1 audio alarm sounds.

The pump continues delivery until the STOP/PROGRAM key is pressed or until the EMPTY alarm sounds.

STEP 11: PROGRAMMING STANDBY TIME

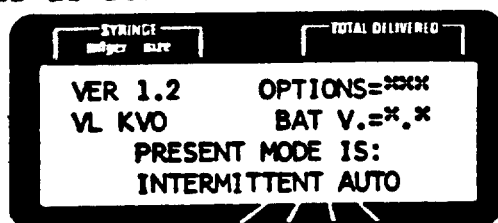
See APPENDIX 1 for specific details regarding this feature.

STEP 1: INTERMITTENT AUTOMATIC

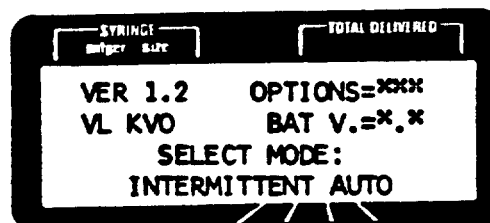
Introduction

The INTERMITTENT AUTO mode requires entry of at least three parameters -- DOSE VOLUME (DV), DELIVERY TIME (DT), and the TIME BETWEEN DOSES (TB). The rate in ml per hour calculates automatically. VOLUME LIMIT (VL) and KVO can be custom programmed. In this infusion mode the pump automatically administers the DV over the DT at intervals established by the TB. The TB includes the DT. (Use this mode for automatic delivery of multiple doses.)

When the pump is turned ON, lines 3 and 4 of the LCD display appear as follows:



If "PRESENT MODE IS" appears, no other infusion modes were custom programmed.

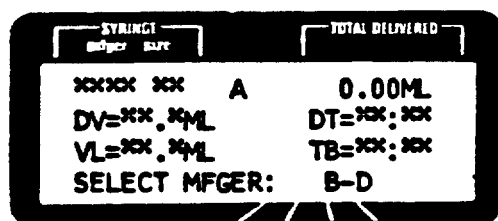


If "SELECT MODE" appears, other infusion modes can be selected by using the SELECT key. To select INTERMITTENT AUTOMATIC, press ENTER. (See Section V, Step 3, page 16-18).

STEP 2: PROGRAMMING SYRINGE MANUFACTURER

NOTE: The "A" in the first line identifies the automatic mode.

NOTE: If a SYRINGE MANUFACTURER is custom programmed, the pump automatically advances to LOAD SYRINGE. Entry into the custom program mode allows a syringe manufacturer change.



Press SELECT key to make the choices appear on the LCD. Repeated presses of the SELECT key display the available choices. For example, B-D refers to Becton-Dickinson, Mono refers to Monoject and Teru refers to Terumo.

SYRINGE		TOTAL DELIVERED	
number	size		
XXXXX XXX	A	0.00ML	
DV=XXX.XML		DT=XXX.XXX	
VL=XXX.XML		TB=XXX.XXX	
SELECT MFGER: MONO			



Press ENTER to program your selection. NOTE: The SYRINGE MANUFACTURER appears on the LCD and the pump automatically advances to the next programmable item.

NOTE: Turn the main power off and start over to correct an inadvertent misentry of the Syringe Manufacturer. A correction is possible only if SELECT MANUFACTURER appears on the LCD.

IMPORTANT: Verify that the syringe manufacturer on the LCD is the same as the syringe in use. Failure to use the listed manufacturer could result in inaccurate delivery.

STEP 3: PROGRAMMING SYRINGE SIZE

SYRINGE		TOTAL DELIVERED	
number	size		
MONO XXX	A	0.00ML	
DV=XXX.XML		DT=XXX.XXX	
VL=XXX.XML		TB=XXX.XXX	
LOAD SYRINGE			

The fourth line of the LCD flashes "LOAD SYRINGE" -- "PRESS enter."

If the syringe is not already loaded onto the pump, load the syringe as instructed (see Section V, page 11-13).

SYRINGE		TOTAL DELIVERED	
number	size		
MONO XXX	A	0.00ML	
DV=XXX.XML		DT=XXX.XXX	
VL=XXX.XML		TB=XXX.XXX	
PRESS enter			



Once the syringe is properly loaded, press the ENTER key. The pump will automatically enter the correct syringe size and advance to the next programmable item.

IMPORTANT: Always confirm that the syringe size stated on the LCD agrees with the size of the syringe loaded on the pump. Failure to do so could result in inaccurate delivery.

STEP 4A - PROGRAMMING THE VOLUME LIMIT (CUSTOM PROGRAMMABLE)

If VOL. LIMIT does not appear on the LCD, it was not custom programmed; skip to step 6.

The VOLUME LIMIT (VL) feature allows delivery of a specific preprogrammed fluid volume from any size syringe. Therefore, the volume in the syringe can be greater than the volume to be infused. The pump stops automatically when the VL amount is reached.

SYRINGE		TOTAL DELIVERED	
size	type		
MONO 60	A	0.00ML	
DV=XX.XML		DT=XX:XX	
		TB=XX:XX	
VOL. LIMIT=		59.2 ML	



Program the VL with the RATE SELECTION key(s). Continuously pressing the RATE SELECTION key(s) automatically advances the number.

Press ENTER to program the desired VL. The LCD automatically advances.

NOTE: If the VL exceeds the syringe capacity, the LCD will display INVALID NUMBER and show the highest possible VL programmable for the syringe selected.

STEP 4B: PROGRAMMING NO VOLUME LIMIT

SYRINGE		TOTAL DELIVERED	
size	type		
MONO 60	A	0.00ML	
DV=XX.XML		DT=XX:XX	
		TB=XX:XX	
VOL. LIMIT=		00.0 ML	



A VL set at 00.0 eliminates VL as a previously programmed feature for this infusion. Press ENTER.


The VL disappears from the LCD for this infusion and the LCD automatically advances.

**STEP 5A: PROGRAMMING KVO (KEEP VEIN OPEN) RATE
(CUSTOM PROGRAMMABLE)**

If KVO does not appear on the LCD during step 1, it was not custom programmed; skip to step 6.

The KVO feature allows delivery of a KVO (keep vein open) rate after the specified delivery is administered.

SYRINGE		TOTAL DELIVERED	
ml/hr	ml		
MONO 60	A	0.00ML	
DV=XX.XML		DT=XX:XX	
VL=59.2ML		TB=XX:XX	
KVO=		0.5ML/HR	



Program the KVO with the RATE SELECTION key(s). Continuously pressing the RATE SELECTION key(s) automatically advances the number.



Press enter to program desired KVO. The LCD automatically advances.

SYRINGE		TOTAL DELIVERED	
ml/hr	ml		
MONO 60	A	0.00ML	
DV=XX.XML		DT=XX:XX	
VL=59.2ML*		TB=XX:XX	
KVO=		00.0 ML	

NOTE: The actual KVO rate does not display on the LCD. When a KVO rate is programmed, an asterisk follows the VL line.

STEP 5B: PROGRAMMING NO KVO RATE

SYRINGE		TOTAL DELIVERED	
ml/hr	ml		
MONO 60	A	0.00ML	
DV=XX.XML		DT=XX:XX	
VL=59.2ML		TB=XX:XX	
KVO=		0.0ML/HR	

A KVO set at 0.0 eliminates KVO as a previously programmed feature for this infusion. Press ENTER.



The asterisk by the VL disappears from the LCD and the KVO is not active for this infusion.

STEP 6: PROGRAMMING DOSE VOLUME (DV)

SYRINGE ml/gpr rate		TOTAL DELIVERED
MONO 60	A	0.00ML
VL=59.2ML*	DT=XX:XX	
DOSE VOL.=	TB=XX:XX	
		00.0 ML

Press the appropriate RATE SELECTION key(s) to program a DOSE VOLUME (DV). NOTE: Continuously pressing the RATE SELECTION key(s) automatically advances the number.

SYRINGE ml/gpr rate		TOTAL DELIVERED
MONO 60	A	0.00ML
VL=59.2ML*	DT=XX:XX	
DOSE VOL.=	TB=XX:XX	
		12.0 ML



Press ENTER key to enter the desired DV. The LCD automatically advances.

STEP 7: PROGRAMMING DELIVERY TIME (DT)

SYRINGE ml/gpr rate		TOTAL DELIVERED
MONO 60	A	0.00ML
DV=12.0ML	DT=XX:XX	
VL=59.2ML*	TB=XX:XX	
DEL. TIME=		00:00

Press the appropriate RATE SELECTION key(s) to program a DELIVERY TIME (DT). NOTE: Continuously pressing the RATE SELECTION key(s) automatically advances the number.

SYRINGE ml/gpr rate		TOTAL DELIVERED
MONO 60	A	0.00ML
DV=12.0ML	DT=XX:XX	
VL=59.2ML*	TB=XX:XX	
DEL. TIME=		00:30



Press ENTER key to enter the DT. The LCD automatically advances.

NOTE: INVALID NUMBER displays on the LCD when an invalid rate entry occurs. The fastest possible infusion time will appear for the DV selected.

STEP 8: PROGRAMMING THE TIME BETWEEN DELIVERIES (TB)

SYRINGE		TOTAL DELIVERED	
ml/gpr	rate		
MONO 60	A	0.00ML	
DV=12.0ML		DT=00:30	
VL=59.2ML*			
TIME BETW=		00:00	

SYRINGE		TOTAL DELIVERED	
ml/gpr	rate		
MONO 60		0.00ML	
DV=12.0ML		DT=00:30	
VL=59.2ML*			
TIME BETW=		06:00	



SYRINGE		TOTAL DELIVERED	
ml/gpr	rate		
MONO 60	A	0.00ML	
DV=12.0ML		DT=00:30	
VL=59.2ML*		TB=06:00	
RATE=		24.00ML/HR	

To program the TIME BETWEEN (TB) deliveries in hours and minutes (e.g., HRS:MINS), press the appropriate RATE SELECTION key(s). NOTE: Continuously pressing the RATE SELECTION key(s) automatically advances the number.

Press ENTER to enter the desired TB. The LCD automatically advances.

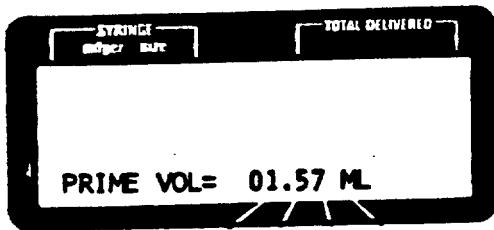
The pump automatically calculates the rate and the information on the LCD is solid (not flashing). The operator can PRIME and/or begin DELIVERY.

STEP 9: PRIMING

SYRINGE		TOTAL DELIVERED	
ml/gpr	rate		
PRIME VOL=		00:00	

Push and hold the PRIME key to purge air from the administration set. The LCD states "PRIME VOL = 00.00 ML" and the pump runs at its fastest rate. After approximately 16 seconds elapses, a continuous tone (#3) sounds. However, the pump continues to prime when the key is held down. NOTE: The amount delivered while priming is NOT counted

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by the TOTAL VOLUME DELIVERED counter. However, the amount delivered is shown on the prime volume counter.



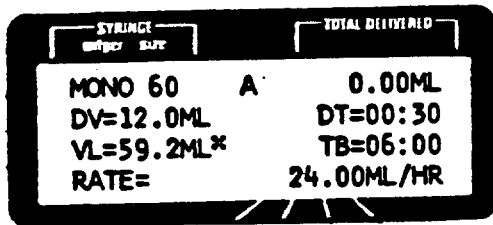
NOTE: The PRIME function only activates when the pump is in the STOP/PROGRAM MODE and all other functions are entered (e.g., Syringe Manufacturer, Syringe Size, Volume Limit, KVO and Rate).

IMPORTANT: The PRIME function should always be utilized when placing a newly filled syringe on the pump or when attaching an infusion set.

IMPORTANT: When PRIMING, if a small bore extension set is being used (i.e., Medfusion's Mini-Vol Set), the OCCLUSION ALARM may actuate. Continue to press PRIME. The OCCLUSION ALARM should clear.

Several attempts may be required to fully PRIME the infusion set. To simplify PRIMING a small bore set, intermittently press and release the PRIME key versus pressing and holding it continuously. Medfusion's slightly larger tubing eliminates the above occurrence.

STEP 10A: DELIVERY



Press the DELIVER key to begin the infusion. The LCD will not flash and the green LED deliver light begins to blink.

In the DELIVERY MODE, all keys are inactive except the Alarm ON/OFF key and the STOP/PROGRAM key.

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STEP 10B: RUNNING VOLUME (ONLY IF VL IS PROGRAMMED)

SYRINGE		TOTAL DELIVERED	
indger	size		
MONO 60	A	0.53ML	
DV=12.0ML		DT=00:30	
VL=59.2ML*		TB=06:00	
RV=0.5ML		24.00ML/HR	



Press and hold the DELIVER key during delivery to display the RUNNING VOLUME (RV).

NOTE: The RV records volume delivered since the last VL reset. By comparing the RV to the VL, one can determine how much more fluid must be delivered before reaching the VL.

The RV is reset to zero when any of the following events occur - Change of syringe size, Empty alarm, Reprogram the VL, reset TOT VOL DEL counter to zero, when the VL is reached and the Prime is used.

STEP 11A: STANDBY WITH KVO

After the pump delivers the DV over the DT, it enters the STANDBY mode. The STANDBY TIME displays the time remaining before the next infusion begins. If a KVO rate is programmed, it will be in effect during the STBY time. Both the STOP/PROGRAM and DELIVER LEDs are out (i.e., not blinking) during the STBY time.

SYRINGE		TOTAL DELIVERED	
indger	size		
MONO 60		12.00ML	
DV=12.0ML		DT=00:30	
VL=59.2ML*		TB=06:00	
KVO=0.5		STBY=05:30	



The STANDBY TIME of 5HRS:30MINS indicates that the 30 minute infusion just ended. The STOP/PROGRAM and DELIVER LED do not blink.

Press DELIVER to review RV.

SYRINGE		TOTAL DELIVERED	
indger	size		
MONO 60	A	12.04ML	
DV=12.0ML		DT=00:30	
VL=59.2ML*		TB=06:00	
RV=12.0ML		STBY=05:25	

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SYRINGE		TOTAL DELIVERED	
ml/gtr	rate		
MONO 60	A	13.25ML	
DV=12.0ML		DT=00:30	
VL=59.2ML*		TB=06:00	
KVO=0.5		STBY=03:00	

STANDBY TIMER continues to count down.

NOTE: When STBY equals 00:00, go to Step 11C.

STEP 11B: STANDBY WITHOUT KVO

SYRINGE		TOTAL DELIVERED	
ml/gtr	rate		
MONO 60	A	12.00ML	
DV=12.0ML		DT=00:30	
VL=59.2ML		TB=06:00	
		STBY/NEXT DEL=05:30	



After the pump delivers the DV over the DT, it enters the STANDBY MODE. The STANDBY TIME displays the time remaining before the next infusion begins.

NOTE: Since a KVO rate is not programmed, both the STOP/PROGRAM and DELIVER LEDs do not blink during the STBY TIME.

STEP 11C: AUTOMATIC DELIVERY BEGINS

SYRINGE		TOTAL DELIVERED	
ml/gtr	rate		
MONO 60	A	14.75ML	
DV=12.0ML		DT=00:30	
VL=54.2ML*		TB=06:00	
RATE=		24.00ML/HR	

When the STANDBY TIME equals 00:00, the DV is given over the DT.

STEP 12A: STOP DELIVERY

SYRINGE		TOTAL DELIVERED	
ml/gtr	rate		
MONO 60	A	15.23ML	
DV=12.0ML		DT=00:30	
VL=59.2ML*		TB=06:00	
RATE=		24.00ML/HR	



Press the STOP/PROGRAM key to stop the infusion. The STOP/PROGRAM LED blinks and a slow intermittent #1 audio alarm sounds.

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A delivery can also be interrupted by the occurrence of an alarm (e.g., occlusion, depleted battery, syringe pops out). Correct the alarm and press DELIVER key to resume. The remaining DV is given at the proper rate. Time does not accumulate during the stopped period.

STEP 12B: END OF DELIVERY - VOLUME LIMIT (VL) WITHOUT KVO

SYRINGE		TOTAL DELIVERED	
ml/hr	rate		
MONO 60	A	59.20ML	
DV=12.0ML		DT=00:30	
VL=59.2ML		TB=06:00	
RATE=		24.00ML/HR	

When the programmed VL is reached, the number 2 audio alarm sounds, the VL LED lights, the RV=VL, and the STOP/PROGRAM LED blinks, indicating that the pump stops delivery.



NOTE: The VL equals the TOTAL VOLUME DELIVERED readout only during the administration of the first infusion. To continue the infusion, press DELIVER. The VOLUME LIMIT ALARMS reset to zero (RV=0.0 ml) and resume when the programmed amount is delivered. For example, if two VL amounts are delivered, the TOTAL VOLUME DELIVERED amount equals twice the VL amount.

STEP 12C: END OF DELIVERY - VOLUME LIMIT WITH KVO

SYRINGE		TOTAL DELIVERED	
ml/hr	rate		
MONO 60	A	59.20ML	
DV=12.0ML		DT=00:30	
VL=59.2ML		TB=06:00	
KVO RATE=		0.5ML/HR	

When the programmed VL is reached, the pump automatically switches to the KVO rate, the VOLUME LIMIT LED lights and a type 1 audio alarm sounds at the custom programmed alarm delay interval.

The pump continues delivery until the STOP/PROGRAM key is pressed or until the EMPTY alarm sounds.

STEP 13: RESET STANDBY TIMER

The STANDBY TIMER can be reset to zero so that the next infusion can begin immediately.

SYRINGE		TOTAL DELIVERED	
ml/hr	rate		
MONO 60	A	14.71ML	
DV=12.0ML		DT=00:30	
VL=59.2ML		TB=06:00	
KVO=0.5		STBY=00:05	

Press STOP/PROGRAM, then press the FUNCTION key.

NOTE: RUNNING VOLUME (RV) equals 14.7 ml.



SYRINGE		TOTAL DELIVERED	
ml/hr	rate		
MONO 60	A	14.71ML	
DV=12.0ML		DT=00:30	
VL=59.2ML		TB=06:00	
RESET STBY TIMER			

The LCD alternates between "RESET STBY TIMER" and "PRESS ENTER". To reset the timer, press ENTER. Press DELIVER key to begin the next infusion.

SYRINGE		TOTAL DELIVERED	
ml/hr	rate		
MONO 60	A	14.71ML	
DV=12.0ML		DT=00:30	
VL=59.2ML		TB=06:00	
PRESS enter			



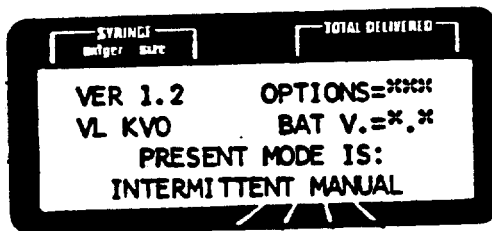
669

STEP 1: INTERMITTENT MANUAL

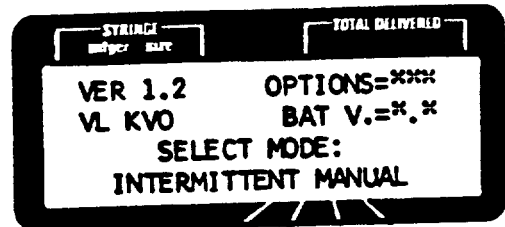
Introduction

The INTERMITTENT MANUAL mode requires entry of at least three parameters -- DOSE VOLUME (DV), DELIVERY TIME (DT), and the TIME BETWEEN DOSES (TB). The rate in mls per hour automatically calculates. Both VOLUME LIMIT (VL) and KVO can be custom programmed. In this infusion mode the pump does not automatically administer the DV over the DT at intervals established by the TB. The DT is included within the TB. Use this mode for manually initiated delivery of multiple doses.

When the pump is turned ON, lines 3 and 4 of the LCD display appear as follows:



If "PRESENT MODE IS" appears, no other infusion modes were custom programmed.

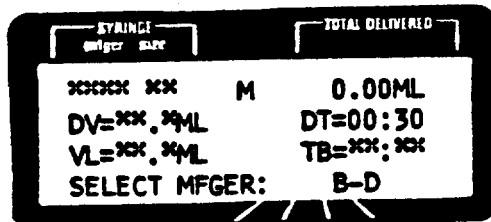


If "SELECT MODE" appears, other infusion modes can be selected by using the SELECT key. To select INTERMITTENT MANUAL, press ENTER. (See Section V, Step 3, page 16-18).

STEP 2: PROGRAMMING SYRINGE MANUFACTURER

NOTE: The "M" in the first line identifies the manual mode.

NOTE: If a syringe manufacturer is custom programmed, the pump automatically advances to LOAD SYRINGE. Entry into the custom program mode allows a syringe manufacturer change.



Press SELECT key to make the choices appear on the LCD. Repeated presses of the SELECT key display the available choices. For example, B-D refers to Becton-Dickinson, Mono refers to Monoject and Teru refers to Terumo.



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SYRINGE mfgcr size		TOTAL DELIVERED
XXXXX XX	M	0.00ML
DV=XX.XML		DT=00:00
VL=XX.XML		TB=XX:XX
SELECT MFGER: MONO		



Press ENTER to program your selection. NOTE: The SYRINGE MANUFACTURER appears on the LCD and the pump automatically advances to the next programmable item.

NOTE: Turn the main power off and start over to correct an inadvertent misentry of the Syringe Manufacturer. A correction is possible only if SELECT MANUFACTURER appears on the LCD.

IMPORTANT: Verify that the syringe manufacturer on the LCD is the same as the syringe in use. Failure to use the listed manufacturer could result in inaccurate delivery.

STEP 3: PROGRAMMING SYRINGE SIZE

SYRINGE mfgcr size		TOTAL DELIVERED
MONO XX	M	0.00ML
DV=XX.XML		DT=00:00
VL=XX.XML		TB=XX:XX
LOAD SYRINGE		

The fourth line of the LCD flashes "LOAD SYRINGE" -- "PRESS enter."

If the syringe is not already loaded onto the pump, load the syringe as instructed (see Section V, page 11-13).

SYRINGE mfgcr size		TOTAL DELIVERED
MONO XX	M	0.00ML
DV=XX.XML		DT=00:00
VL=XX.XML		TB=XX:XX
PRESS enter		



Once the syringe is properly loaded, press the ENTER key. The pump will automatically enter the correct syringe size and advance to the next programmable item.

IMPORTANT: Always confirm that the syringe size stated on the LCD agrees with the size of the syringe loaded on the pump. Failure to do so could result in inaccurate delivery.

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STEP 4A - PROGRAMMING THE VOLUME LIMIT (CUSTOM PROGRAMMABLE)

If VOL. LIMIT does not appear on the LCD, it was not custom programmed, skip to step 6.

The VOLUME LIMIT (VL) feature allows delivery of a specific preprogrammed fluid volume from any size syringe. Therefore, the volume in the syringe can be greater than the volume to be infused. The pump stops automatically when the VL amount is reached.

SYRINGE mL/gal		TOTAL DELIVERED	
MONO 60	M	0.00ML	
DV=XX.XX		DT=00:00	
		TB=XX:XX	
VOL. LIMIT=		42.0 ML	



Program the VL with the RATE SELECTION key(s). Continuously pressing the RATE SELECTION key(s) automatically advances the number.

Press enter to program the desired VL. The LCD automatically advances.

NOTE: If the VL exceeds the syringe capacity, the LCD will display INVALID NUMBER and show the highest possible VL programmable for the syringe selected.

STEP 4B: PROGRAMMING NO VOLUME LIMIT

SYRINGE mL/gal		TOTAL DELIVERED	
MONO 60	M	0.00ML	
DV=XX.XX		DT=00:00	
		TB=XX:XX	
VOL. LIMIT=		00.0 ML	



A VL set at 00.0 eliminates VL as a previously programmed feature for this infusion. Press ENTER.

The VL disappears from the LCD for this infusion and the LCD automatically advances.

**STEP 5A: PROGRAMMING KVO (KEEP VEIN OPEN) RATE
(CUSTOM PROGRAMMABLE)**

If KVO does not appear on the LCD during Step 1, it was not custom programmed; skip to Step 6.

The KVO feature allows delivery of a KVO rate after the specified VOLUME LIMIT is administered.

SYRINGE ml/hr size		TOTAL DELIVERED
MONO 60	M	0.00ML
DV=xx.xML		DT=00:00
VL=42.0		TB=xx:xx
KVO=		0.5ML/HR

▲ ▲ ▲ ▲

Program the KVO with the RATE SELECTION key(s). Continuously pressing the RATE SELECTION key(s) automatically advances the number.



Press enter to program desired KVO. The LCD automatically advances.

SYRINGE ml/hr size		TOTAL DELIVERED
MONO 60	M	0.00ML
		DT=00:00
VL=42.0ML*		TB=xx:xx
DOSE VOL.=		00.0 ML

NOTE: The actual KVO rate cannot be displayed on the LCD. Whenever a KVO rate is programmed, an asterisk follows the VL line.

STEP 5B: PROGRAMMING NO KVO RATE

SYRINGE ml/hr size		TOTAL DELIVERED
MONO 60	M	0.00ML
DV=xx.xML		DT=00:00
VL=42.0ML*		TB=xx:xx
KVO=		0.0ML/HR

A KVO set at 0.0 eliminates KVO as a previously programmed feature for this infusion. Press ENTER.



The asterisk by the VL disappears and the KVO is not active for this infusion.

JB

STEP 6: PROGRAMMING DOSE VOLUME (DV)

SYRINGE		TOTAL DELIVERED
major	rate	
MONO 60	M	0.00ML
VL=42.0*		DT=00:00
DOSE VOL.=		TB=xx:xx
		00.0 ML

SYRINGE		TOTAL DELIVERED
major	rate	
MONO 60	M	0.00ML
VL=42.0ML*		DT=00:00
DOSE VOL.=		TB=xx:xx
		20.0 M



Press the appropriate RATE SELECTION key(s) to program a DOSE VOLUME (DV). NOTE: Continuously pressing the RATE SELECTION key(s) automatically advances the number.

Press ENTER key to enter the desired DV. The LCD automatically advances.

STEP 7: PROGRAMMING DELIVERY TIME (DT)

SYRINGE		TOTAL DELIVERED
major	rate	
MONO 60	M	0.00ML
DV=20.0ML		
VL=42.0ML*		TB=xx:xx
DEL. TIME=		00:00

SYRINGE		TOTAL DELIVERED
major	rate	
MONO 60	M	0.00ML
DV=20.0ML		
VL=42.0ML*		TB=xx:xx
DEL. TIME=		04:00



Press the appropriate RATE SELECTION key(s) to program a DELIVERY TIME (DT). NOTE: Continuously pressing the RATE SELECTION key(s) automatically advances the number.

Press ENTER key to enter the desired DT. The LCD automatically advances.

NOTE: INVALID NUMBER displays on the LCD when an invalid rate entry occurs. The fastest possible infusion time will appear for the DV selected.

mf

STEP 8: PROGRAMMING THE TIME BETWEEN DELIVERIES (TB)

SYRINGE		TOTAL DELIVERED	
mg/ml	size		
MONO 60	M	0.00ML	
DV=20.0ML		DT=04:00	
VL=42.0ML*			
TIME BETW=		00:00	

To program the TIME BETWEEN (TB) deliveries in hours and minutes (e.g., HRS:MINS), press the appropriate RATE SELECTION key(s). NOTE: Continuously pressing the RATE SELECTION key(s) automatically advances the number.

SYRINGE		TOTAL DELIVERED	
mg/ml	size		
MONO 60	M	0.00ML	
DV=20.0ML		DT=04:00	
VL=42.0ML*			
TIME BETW=		06:00	



Press ENTER to enter the desired TB. The LCD automatically advances.

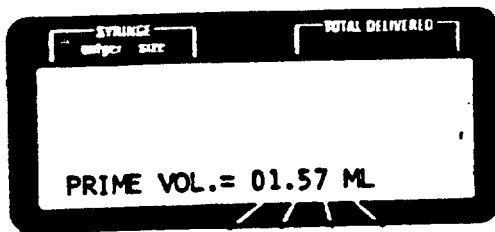
SYRINGE		TOTAL DELIVERED	
mg/ml	size		
MONO 60	M	0.00ML	
DV=20.0ML		DT=04:00	
VL=42.0ML*		TB=06:00	
RATE=		5.000ML/HR	

The pump automatically calculates the rate and the information on the LCD is solid (not flashing). The operator can PRIME and/or begin DELIVERY.

STEP 9: PRIMING

SYRINGE		TOTAL DELIVERED	
mg/ml	size		
PRIME VOL= 00.00 ML			

Push and hold the PRIME key to purge air from the administration set. The LCD states "PRIME VOL = 00.00 ML" and the pump runs at its fastest rate. After approximately 16 seconds elapses, a continuous tone (#3) sounds. However, the pump continues to prime when the key is held down.



NOTE: The amount delivered while priming is NOT counted by the TOTAL VOLUME DELIVERED counter. However, the amount delivered is shown on the prime volume counter.

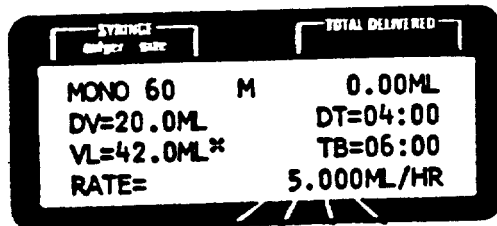
NOTE: The PRIME function only activates when the pump is in the STOP/PROGRAM MODE and all other functions are entered (e.g., Syringe Manufacturer, Syringe Size, Volume Limit, KVO and Rate).

IMPORTANT: The PRIME function should always be utilized when placing a newly filled syringe on the pump or when attaching an infusion set.

IMPORTANT: When PRIMING, if a small bore extension set is being used (i.e., Medfusion's Mini-Vol Set), the OCCLUSION ALARM may actuate. Continue to press PRIME. The OCCLUSION ALARM should clear.

Several attempts may be required to fully PRIME the infusion set. To simplify PRIMING a small bore set, intermittently press and release the PRIME key versus pressing and holding it continuously. Medfusion's slightly larger tubing eliminates the above occurrence.

STEP 10A: DELIVERY



Press the DELIVER key to begin the infusion. The LCD will not flash and the green LED DELIVER light begins to blink.

In the DELIVERY MODE, all keys are inactive except the Alarm ON/OFF key and the STOP/PROGRAM key.

STEP 10B: RUNNING VOLUME (ONLY IF VL IS PROGRAMMED)

SYRINGE		TOTAL DELIVERED	
size	rate		
MONO 60	M	0.53ML	
DV=20.0ML		DT=04:00	
VL=42.0ML*		TB=06:00	
RV=0.5ML		5.000ML/HR	



Press and hold the DELIVER key during delivery to display the RUNNING VOLUME (RV).

NOTE: The RV records volume delivered since the last VL reset. By comparing the RV to the VL, one can determine how much more fluid must be delivered before reaching the VL.

The RV is reset to zero when any one of the following events occur - Change in syringe size, Empty alarm, Reprogram the VL, reset TOT VOL DEL counter to zero, when the VL is reached and when Prime is used.

STEP 11A: STANDBY WITH KVO

After the pump delivers the DV over the DT, it enters the STANDBY mode. The STANDBY TIME displays the time remaining before the next infusion should begin. The pump will not automatically begin this infusion. If a KVO rate is programmed, it will be in effect during the STBY time. The DELIVER LED continues to blink during the STBY time.

SYRINGE		TOTAL DELIVERED	
size	rate		
MONO 60	M	20.00ML	
DV=20.0ML		DT=04:00	
VL=42.0ML*		TB=06:00	
KVO=0.5		STBY=02:00	



The STANDBY TIME of 5HRS:30MINS indicates that the infusion just ended. The STOP/PROGRAM and DELIVER LED do not blink.

Press DELIVER to review RV.

SYRINGE		TOTAL DELIVERED	
ml/hr	size		
MONO 60	M	20.71ML	
DV=20.0ML		DT=04:00	
VL=42.0ML*		TB=06:00	
RV=20.7ML		STBY=00:35	

STANDBY TIMER continues to count down.

NOTE: When STBY equals 00:00, go to Step 11C.

STEP 11B: STANDBY WITHOUT KVO

SYRINGE		TOTAL DELIVERED	
ml/hr	size		
MONO 60	M	20.00ML	
DV=20.0ML		DT=04:00	
VL=42.0ML		TB=06:00	
		STBY/NEXT DEL=02:00	

After the pump delivers the DV over the DT, it enters the STANDBY MODE. The STANDBY TIME displays the time remaining before the desired start time of the next infusion.

When a KVO rate is not programmed, both the STOP/PROGRAM and DELIVER LEDs do not blink during the STBY time.

STEP 11C: NEXT DELIVERY ALERT

SYRINGE		TOTAL DELIVERED	
ml/hr	size		
MONO 60	M	21.00ML	
DV=20.0ML		DT=04:00	
VL=42.0ML*		TB=06:00	
RATE=		5.000ML/HR	

When the STANDBY TIME equals 00:00, the DV will not be automatically given over the DT. The STOP/PROGRAM LED blinks. The #1 audio sounds. Press DELIVER key to initiate the next delivery.



STEP 12A: STOP DELIVERY

SYRINGE		TOTAL DELIVERED	
ml/hr	size		
MONO 60	M	19.25ML	
DV=20.0ML		DT=04:00	
VL=42.0ML*		TB=06:00	
RATE=		5.000ML/HR	



Press the STOP/PROGRAM key to stop the infusion. The STOP/PROGRAM LED blinks and a slow intermittent #1 audio alarm sounds.

A delivery can also be interrupted by the occurrence of an alarm (e.g., occlusion, depleted battery, syringe pops out). Correct the alarm and press DELIVER key to resume. The remaining DV is given at the proper rate. Time does not accumulate during the stopped period.

STEP 12B: END OF DELIVERY - VOLUME LIMIT WITHOUT KVO

SYRINGE		TOTAL DELIVERED	
ml/hr	rate		
MONO 60	M	40.00ML	
DV=20.0ML		DT=04:00	
VL=40.0ML		TB=06:00	
RATE=		5.000ML/HR	

When the programmed VL is reached, the number 2 audio alarm sounds, the VL LED lights, the RV=VL, and the STOP/PROGRAM LED blinks, indicating that the pump stops delivery.

NOTE: The VL equals the TOTAL VOLUME DELIVERED readout only during the administration of the first infusion. To continue the infusion, press DELIVER. The VOLUME LIMIT ALARMS reset to zero (RV=0.0 ml) and resume when the programmed amount is delivered. For example, if two VL amounts are delivered, the TOTAL VOLUME DELIVERED amount equals twice the VL amount.

STEP 12C: END OF DELIVERY -- VOLUME LIMIT WITH KVO

SYRINGE		TOTAL DELIVERED	
ml/hr	rate		
MONO 60	M	42.00ML	
DV=20.0ML		DT=04:00	
VL=42.0ML		TB=06:00	
KVO RATE=		0.5ML/HR	

When the programmed VL is reached, the pump automatically switches to the KVO rate, the VOLUME LIMIT LED lights and a type 1 audio alarm sounds at the custom programmed alarm delay interval.

The pump continues delivery until the STOP/PROGRAM key is pressed or until the EMPTY alarm sounds.

STEP 13: RESET STANDBY TIMER

The STANDBY TIMER can be reset to zero so that the next infusion can begin immediately.

SYRINGE		TOTAL DELIVERED	
ml/hr	rate		
MONO 60	M	20.96ML	
DV=20.0ML		DT=04:00	
VL=42.0ML		TB=06:00	
KVO=0.5		STBY=00:05	

Press STOP/PROGRAM, then press the FUNCTION key.



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function

SYRINGE		TOTAL DELIVERED	
mL per	size		
MONO 60	M	20.96ML	
DV=20.0ML		DT=04:00	
VL=42.0ML		TB=06:00	
RESET STBY TIMER			

The LCD alternates between "RESET STBY TIMER" and "PRESS enter." To reset the timer, press ENTER. Press DELIVER key to restart the infusion.

SYRINGE		TOTAL DELIVERED	
mL per	size		
MONO 60	M	20.96ML	
DV=20.0ML		DT=04:00	
VL=42.0ML		TB=06:00	
PRESS enter			

enter

deliver

**Section VII
OTHER KEY FUNCTIONS**

A. ALARM OFF/ON

To temporarily silence an audio alarm, press the AUDIO OFF/ON key. The alarm stops but the appropriate LED remains lit. After approximately 5 or 60 minutes, the audio alarm automatically turns back "ON." (The time delay of 5 or 60 minutes is custom programmed at the factory or by qualified biomedical personnel.) To accomplish re-activation of the audio alarm, press the ALARM OFF/ON key for a second time to accomplish re-activation of the audio alarm.

NOTE: The SYSTEM MALFUNCTION alarm is only silenced by turning off the main power.

B. RESET TOTAL VOLUME

The RESET TOTAL VOLUME key is active only when the pump is in the STOP/PROGRAM mode. To RESET the TOTAL VOLUME to 000.00, press the key. Each time the main power is switched "ON," the TOTAL VOLUME automatically zeros.

C. REPROGRAMMING RATE

Press the STOP/PROGRAM key to stop the delivery. Press any RATE key to start the rate flashing (i.e., now programmable). Once the rate begins to flash, change to the desired rate. Commence delivery by pressing either the (1) ENTER key, then DELIVER key or (2) by pressing the DELIVER key twice.

Upon commencing delivery, the green LED blinks and all keys except ALARM OFF/ON and STOP/PROGRAM inactivate.

D. FUNCTION

In the CONTINUOUS and VOLUME OVER TIME modes, the FUNCTION key is used to program a standby time so an infusion may be temporarily discontinued.

In the INTERMITTENT AUTO and INTERMITTENT MANUAL modes, the FUNCTION key is used to reset the STANDBY TIMER to zero.

In addition, it is reserved for future software versions of the pump.

E. BACKLIGHT

During battery operation, the LCD backlight will come on for about 15 seconds if this key or any other key is pressed.

F. RATE SELECTION KEY

Simultaneously pressing any two rate selection keys resets parameter to 0 in cases of inadvertent misentry.

G. PUMP POWER SWITCH

In addition to turning pump on/off, this can serve as a means to erase inadvertent misentries so that correct parameters can be entered.



Section VIII
ALARMS/ALERTS

A. INTRODUCTION

The pump incorporates a series of ALARMS which are depicted in Table I.

NOTE: Review Section VII-A for specifics on how the ALARM OFF/ON key functions.

B. PROCEDURE FOR CORRECTING OCCLUSION ALARM

Trouble-shoot by first checking for:

1. Kinks in tubing
2. Stop cocks and clamps which are turned off--prohibiting flow
3. Clotted IV catheter or needle
4. Something preventing movement of the Syringe Driver

By correcting the cause of the occlusion, the pressure is relieved and the pump restarts by merely pressing the DELIVER key.

NOTE: The pump STOPS INFUSING if an occlusion alarm occurs.

C. PROCEDURE FOR CORRECTING SYSTEM MALFUNCTION

This alarm indicates that something has disrupted the operation of the microprocessor. Failures, which would activate this alarm, are over and under deliveries and electrical component failures.

IMPORTANT: If this alarm occurs, remove the pump from service and consult manufacturer. Also, RECORD any operating data such as Total Volume Delivered, Infusion Rate, etc. Once the pump is turned OFF, this information is NOT retained.

D. NEAR EMPTY ALARM

The NEAR EMPTY ALARM automatically sounds three (3) beeps approximately ten minutes before the syringe becomes physically empty.

NOTE: The pump continues to deliver after the NEAR EMPTY ALARM sounds.

E. EMPTY ALARM

The EMPTY ALARM'S actuation point is determined by a mathematical formula based on the Syringe Manufacturer and Syringe Size.

Whenever an EMPTY ALARM sounds (Alarm #2), the operator should visually verify that the syringe in use is EMPTY.

The operator must decide to terminate the infusion or replace the syringe with a new supply of infusate.

NOTE: The pump stops delivering when the EMPTY ALARM SOUNDS. The audio #2 alarm may be temporarily silenced by pressing the ALARM OFF/ON key.

F. SYRINGE POPS OUT

This alarm occurs if the syringe is disturbed during the infusion. A type 3 or continuous alarm sounds and the fourth line of the LCD alternates between "PRESS enter" and "SYRINGE POPS OUT!"

To correct, confirm that the syringe is loaded properly, then press ENTER to verify syringe size. Press DELIVER to continue the infusion.

The audio alarm is temporarily silenced by pressing the ALARM OFF/ON key.

G. CHECK CLUTCH

This alarm occurs if the clutch is not engaged to the SYRINGE DRIVER. A type 3 or continuous alarm sounds and the fourth line of the LCD alternates between "PRESS enter" and "CHECK CLUTCH!!"

To correct, make sure the clutch is fully engaged and that the syringe is properly loaded.

Press "ENTER" to confirm CLUTCH check and then DELIVER to continue the infusion.

The audio alarm is temporarily silenced by pressing the ALARM OFF/ON key.



H. INVALID SIZE

This alarm occurs if the syringe loaded on the pump is not the size which is stored in the pump. This alarm cannot always distinguish between the same size syringe for different manufacturers.

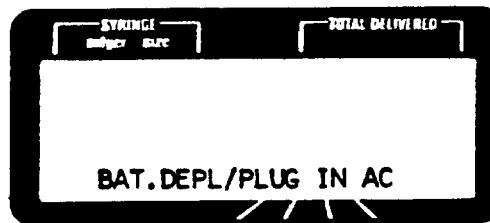
To correct, confirm that the syringe manufacturer programmed is the same as the syringe being utilized. Also verify that the area between the syringe barrel and SYRINGE CLAMP is kept clear of labels, etc.

I. INVALID NUMBER

This LCD message occurs with entry of a parameter which cannot be accepted by the computer. Two beeps sound and the first valid number is displayed. For example, a rate too fast for the syringe selected, a volume limit greater than the volume of the syringe selected, if the Delivery Time is less than or equal to the Time Between Doses, in V/T where the desired delivery time is too fast for the volume chosen, etc.

Section IX
BATTERY POWER

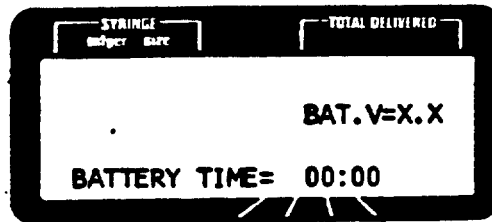
- A. The pump's batteries simultaneously recharge while operating and while the pump is turned OFF but plugged into AC. The batteries cannot be over-charged. The BATTERY CHARGING LED indicates that electricity is reaching the batteries.
- B. If the LOW BATTERY LED lights while the pump is running, the pump should be placed on AC within 30 minutes. However, the pump's operation is not compromised in any way while operating in the low battery state.
- C. If the pump is allowed to reach DEPLETED BATTERY, the LED will flash and #3 audio alarm will sound. The pump is no longer able to continue operating. To continue the infusion, the pump must be plugged into the wall. The LCD appears as described below.
- D. If a depleted battery condition exists upon turning the pump ON, the LCD will state:



The pump must be plugged in and the DELIVER key pressed before commencing operation.

- E. The batteries are being recharged even when the pump is not delivering provided the pump is plugged in and the BATTERY CHARGING LED is on.
- F. The LCD backlight is normally off when the pump is operating on battery power with activation of the BACKLIGHT key (on battery power) The BACKLIGHT stays on for 15 seconds. The backlight is always lit when the pump is operating on AC power.

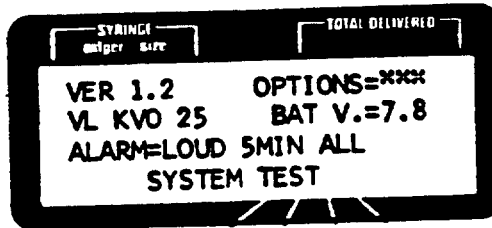
- G. To display the battery recharge time, press and hold both the STOP/PROGRAM and DELIVER keys, then turn the pump on.



Both the recharge time and battery voltage display.

Section X
BATTERY VOLTAGE

- A. To check the charge status of the batteries
1. Unplug the AC adaptor
 2. Turn the pump ON
 3. Review the voltage stated on the LCD



A voltage greater than 8.5 volts indicates a FULL CHARGE. A voltage less than 7.3 volts indicates a LOW BATTERY condition.

Section XI
IV POLE OR RAIL ATTACHMENT

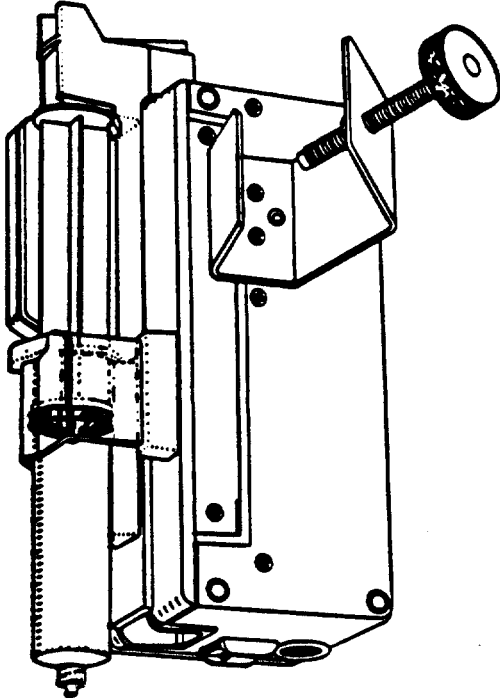
A. INTRODUCTION

All pumps can easily accept the IV clamp using the procedure described below.

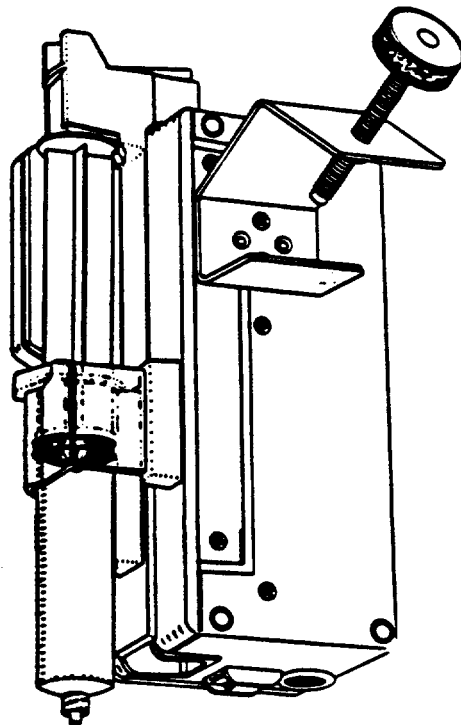
B. ATTACHING IV CLAMP

Orient the IV Clamp either vertically (for IV pole mounting) or horizontally (rail mounting). Use the two #6-32 flat head screws provided to secure the IV clamp to the back of the pump.

Vertical



Horizontal



A handwritten signature or set of initials in the bottom right corner of the page.

Section XII

PRECAUTIONS

- A. Purge all air from the syringe and infusion lines BEFORE connecting to patient.
- B. Verify all programmed settings PRIOR to initiating delivery.
- C. Do not allow fluids to enter the 2001. Immediately wipe off all spills.
- D. Do not use in presence of flammable anesthetics or explosive gases (i.e., in laboratories or in operating rooms where explosive gases are present).
- E. Use only those drugs which are compatible with the disposable syringe selected and the existing environmental conditions.
- F. Do not autoclave or subject the pump to temperatures which exceed 50 degrees C.
- G. Always verify carefully that the syringe is mounted properly. The finger tabs should be secured by the syringe clamp and the syringe plunger end by the syringe driver retainer.
- H. Use only B-D (Becton-Dickinson), Mono (Monoject) and Teru (Terumo) plastic disposable syringes.
- I. If the pump fails to perform as described herein, remove from service and consult the manufacturer.
- J. Verify that the model number and software version of the pump and the instruction manual agree.
- K. This pump is for use only under the direction of qualified medical professionals.
- L. Always use PRIME when mounting a newly filled syringe to remove any mechanical tolerances. Failure to do so may delay the delivery of the infusate and result in a falsely higher TOTAL VOLUME DELIVERED read-out.
- M. The TOTAL VOLUME DELIVERED and the VOLUME LIMIT use separate counters.
- N. Do not use organic solvents to clean the pump.



- O. On the front of this manual is a revision date. If the date is over three (3) years, please contact Medfusion to see if additional information related to this product is available.
- P. Do not place any labels on the syringe that will be covered by the syringe retainer clamp. This clamp must contact the syringe barrel without interference to ensure accurate syringe size sensing.
- Q. Verify that both the manufacturer of the syringe in use and the syringe size coincide with the information displayed on LCD display.

Section XIII

CLEANING

The pump can be cleaned by using a mild soap and water solution applied with a damp cloth. Do not use any unapproved organic-based solvents. Do not immerse.

281

Section XIV
SERVICE AND WARRANTY

Other than cleaning, maintenance must be performed by qualified biomedical personnel at the institution or at Medfusion.

WARRANTY

Medfusion, Inc. warrants to the purchaser that the Syringe Infusion Pump shall be free from defects in material and workmanship for a period of one (1) year from the date of purchase. Medfusion's sole obligation with respect to any such defect is limited to the repair, or at Medfusion's option, replacement of the Syringe Infusion Pump. Purchaser pays return freight charges.

This warranty is made on the condition that prompt notification of a defect is given to MEDFUSION, within the warranty period, and that MEDFUSION shall have the sole right to determine whether a defect exists.

This warranty does not apply to Syringe Pumps that have been partially or completely disassembled, altered, subjected to misuse, negligence, or accident; or operated other than in accordance with the instructions provided by Medfusion.

This warranty represents the exclusive obligation of Medfusion, and the exclusive remedy of the purchaser regarding defects in a Syringe Infusion Pump. THIS WARRANTY IS GIVEN IN LIEU OF ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING THE WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE. No person is authorized to modify, in any manner, Medfusion's obligation as described above.

JAN 7 1994

228

APPENDIX I

PLACING THE 2001 IN STANDBY MODE FOR CONTINUOUS AND VOLUME OVER TIME

The STANDBY MODE allows the operator to temporarily suspend an infusion thereby retaining all pertinent data (e.g. rate, total volume delivered, syringe size, syringe manufacture, etc.). The STANDBY TIMER simply delays the reoccurrence of the standard STOP/PROGRAM audio alarm by the time programmed.

PROGRAMMING

- 1) Confirm that the 2001 is in the continuous or volume over time mode.
- 2) Press STOP/PROGRAM key once to stop the infusion.
- 3) Press FUNCTION key. The last line on the LCD will appear as follows: STBY TIME= 00:00.
- 4) Program the desired STANDBY TIME in hours and minutes (e.g. 03:30 for three hours and thirty minutes) with the RATE keys.
- 5) Press ENTER key to start the timer. The LCD will state "STBY/NEXT DEL = 03:30". The pump will remain in the STOP/PROGRAM mode until the programmed STANDBY TIME elapses. The remaining time is always displayed on the LCD.
- 6) When the STANDBY TIME equals 00:00 (e.g. STBY/NEXT DEL = 00:00) it disappears from the screen, the normal STOP/PROGRAM audio alarm will begin to sound, and the previously programmed RATE will reappear.
- 7) Press DELIVER to begin delivery or repeat steps 3 through 5 to program an additional delay time.

TO CANCEL

- 1) To cancel a previously programmed STANDBY TIME, press the STOP/PROGRAM key to return the pump to its previously programmed setting.
- 2) Press DELIVER key to commence infusion.

APPENDIX II

FLOW RATES

<u>SYRINGE SIZE</u>	<u>MFGR</u>	<u>ML PER HR</u> (In Tenths)		<u>ML PER HR</u> (In Hundredths)	
		<u>Maximum</u>	<u>Minimum</u>	<u>Maximum</u>	<u>Minimum</u>
1.0	B-D	11.00	0.01	11.00	0.01
1.0	Mono	11.00	0.01	11.00	0.01
1.0	Teru	11.00	0.01	11.00	0.01
3.0	B-D	36.00	0.01	36.00	0.01
3.0	Mono	39.60	0.01	39.60	0.01
3.0	Teru	39.60	0.01	39.60	0.01
5.0	B-D	70.00	0.01	70.00	0.01
6.0	Mono	80.80	0.01	80.80	0.01
5.0	Teru	80.80	0.01	80.80	0.01
10.0	B-D	104.0	0.1	99.00	0.1
12.0	Mono	126.0	0.1	99.00	0.1
10.0	Teru	126.0	0.1	99.00	0.1
20.0	B-D	182.0	0.1	99.00	0.1
20.0	Mono	207.0	0.1	99.00	0.1
20.0	Teru	207.0	0.1	99.00	0.1
30.0	B-D	234.0	0.1	99.00	0.1
35.0	Mono	285.0	0.1	99.00	0.1
30.0	Teru	270.0	0.1	99.00	0.1
50/60	B-D	355.0	0.1	99.00	0.1
60.0	Mono	356.0	0.1	99.00	0.1
60.0	Teru	378.0	0.1	99.00	0.1

NOTE: If a MAXIMUM RATE was custom programmed, the following are true (NOTE: MAXIMUM RATE only affects the continuous rate mode.):

1. All syringe sizes can be programmed in hundredths.
2. A rate higher than the MAXIMUM RATE cannot be entered. If attempted, the LCD states INVALID NUMBER.



APPENDIX III

DEFINITIONS

Alarm Temporary Delay Time: A custom programmed delay time of either 5 or 60 minutes that is activated when the alarm key is pressed once.

Alarm Volume: A program option in the CP mode that allows variance of the alarm auditory volume as either loud or soft.

Continuous Infusion Mode: A level of pump operation that allows delivery of a specific fluid volume at a specified rate. (Useful in delivery of a volume of medication at a specific constant rate.)

Custom Program Mode (CP): A level of pump operation that is limited in access by a lockout feature and generally only accessed by healthcare professionals or biomedical engineers to preprogram or customize the pump by selection of the infusion modes, the maximum infusion rate, the alarm volume, the alarm temporary delay time, volume limit, KVO rate, and alarm types.

Delivery Mode: The level of pump operation during which the infusion occurs as initiated by pressing the DELIVER key and indicated by the blinking of the green LED DELIVER Key light. All keys except the ALARM OFF/ON key and STOP/PROGRAM key are inactivated.

Delivery Time (DT): Time in minutes for the dose volume to be delivered.

Dose Volume (DV): Volume (in mls) of dose to be administered (the same as volume limit in the volume/time mode).

Intermittent Auto: A level of pump operation that automatically delivers a specific dose volume over a specified delivery time at intervals established by programming the time between. (Useful for automatic delivery of multiple doses.)

Intermittent Manual: A level of pump operation that delivers a specific dose volume over a specified delivery time at intervals established by programming the time between. However, delivery is not automatic--it must be manually initiated. (Useful in manual delivery of multiple doses.)

Invalid Number: A LCD parameter that indicates what has been programmed is not consistent with other values entered. The highest possible entry that is programmable will be displayed (e.g., if a VL is entered that exceeds the syringe

capacity, the display will show the highest value programmable for the syringe selected).

KVO Rate (KVO): A custom program feature that preprograms a specific "keep vein open" rate to be delivered once the specified volume limit is delivered. (Note: If the KVO exceeds the programmed rate, the pump automatically defers to the lower rate and a KVO cannot be programmed if a VL was not.)

Light Emitting Diode (LED): A red, yellow or green light function available on certain keys of the pump.

Liquid Crystal Display (LCD): The pump screen.

Maximum Infusion Rate: A custom program mode parameter that limits the acceptable programmable rate to the value programmed in the continuous mode. (Allows programming to hundredths of a ml.)

Prime: A level of pump operation that is only activated in the program mode when all other functions have been entered. Priming allows the fluid to be delivered to replace air in the tubing attached to the syringe. The actual priming volume can be verified on the prime volume counter of the LCD. The prime function also eliminates any mechanical tolerances whenever a newly filled syringe is loaded onto the pump.

Running Volume (RV): A recording of total volume delivered since the last volume limit reset. The Volume limit minus running volume equals the volume yet to be delivered.

Standby Mode: The level of pump operation occurring between the completion of one intermittent dose and the beginning of the next intermittent dose. If a KVO rate has been programmed, it will be in effect during this mode.

Standby Time: The time (in hours/minutes) on the LCD display during the standby mode that represents the time remaining before the next infusion begins.

Time Between (TB): A program parameter in the intermittent automatic and manual modes that represent the interval between doses including the dose time in hours and minutes (e.g., for an antibiotic ordered to be infused every 8 hours over 30 minutes, the TB is 8 hours not 7:30).

Total Volume Delivered: Refers to the amount of medication actually delivered during the course of an infusion (however, does not include the volume delivered in the priming mode).

Volume Limit (VL): A custom program feature that preprograms a specific fluid volume to be delivered from any size syringe. Once that limit is delivered, the pump stops.

Volume/Time Mode: A level of pump operation that delivers a specific dose volume over a specified delivery time (useful in delivery of a single dose over a specific time).

User Mode: A level of pump operation that is available to the user of the pump. Level of operation can be limited by custom programming or can allow the user full access to program parameters.

TABLE 1: ALARM/ALERT GRID FOR No. 2001

ALARM OR ALERT	AUDIO (A)	TEMPORARY AUDIO OFF (B)	VISUAL LED (C)	AUTOMATICALLY ADJUSTED	LED MESSAGE	DETAILS TO STOP/PROG	INFUSION AUTOMATICALLY STOPS	WHAT TO DO
STOP/PROGRAM	01	YES	YES-AT SWITCH (R)	N/A	NONE	N/A	YES	PROGRAM OR TURN PUMP OFF
NEAR EMPTY	3 BEEPS	N/A	YES (R)	YES-APPROX. 10 MINUTES FROM EMPTY POINT	NONE	NO	NO	PREPARE TO TERMINATE INFUSION OR LOAD A NEWLY FILLED SYRINGE
EMPTY	02	YES	YES (R)	YES	NONE	YES	YES	TERMINATE INFUSION OR LOAD A NEWLY FILLED SYRINGE
VOLUME LIMIT	02	YES	YES (R)	PROGRAMMED	NONE	YES	YES	TERMINATE INFUSION OR CONTINUE DELIVERY
OCCCLUSION	03	YES	YES (R)	YES	NONE	YES	YES	CORRECT PROBLEM AND PRESS DELIVERY TO RESTART INFUSION
SYSTEM MALFUNCTION	03	NO-HUST TURN OFF MAIN POWER	YES (R)	NONE	SYS MAL	YES	YES	REMOVE UNIT FROM SERVICE AND CONSULT MANUFACTURER
LOW BATTERY	NONE	N/A	YES (R)	YES-APPROX. 30 MINUTES POWER REMAIN	NONE	NO	NO	PLUG INTO MAIN AC AS SOON AS POSSIBLE
DEPLETED BATTERY	03	YES	YES (R)	N/A	PLUG IN AC	YES	YES	PUMP CANNOT INFUSE UNLESS PLUGGED INTO AC--ALLOW TIME FOR BATTERY TO RECHARGE
BATTERY IN USE	NONE	N/A	YES (T)	N/A	NONE	N/A	NO	INFORMATION ONLY
BATTERY CHARGING	NONE	N/A	YES (G)	N/A	NONE	N/A	NO	INFORMATION ONLY
SYRINGE POPS OUT	03	YES	NO	N/A	YES	YES	YES	REENTER SYRINGE SIZE
PRINTING	03 (16 SEC. DELAY)	NO	NO	N/A	PRINTING	N/A	N/A	N/A
DELIVER	NONE	N/A	YES-AT SWITCH (G)	N/A	NONE	N/A	N/A	N/A
VALID KEY PRESS	ONE PECK	NO	N/A	N/A	N/A	N/A	N/A	N/A

(A) ALARM AUDIO 01 IS SHORT BEEPS WITH LONG INTERVALS; 02 SHORT FAST BEEPS; 03 CONT. AS TONE.
(B) TEMPORARY AUDIO OFF RESETS TO AUDIO ON AFTER 5 MINUTES OR 60 MINUTES (OFFLINE PROGRAMMABLE) OR THE AUDIO CAN BE TURNED BACK ON BY PRESSING THE AUDIO
OFF/ON KEY FOR A SECOND TIME.

(C) DENOTES LED COLOR (E.G., (0) GREEN; (2) RED; (Y) YELLOW).

N/A = NOT APPLICABLE.

OPERATIONS MANUAL
FOR
MEDFUSION SYRINGE INFUSION
PUMP
MODEL 2001 (Software 1.2)

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236

300

Summary of SETs

Summary of Safety and Effectiveness